



Sample Models, Program Specifications, Testing Scenarios, and User Documentation for
Fully Integrated Research Standards & Technology (FIRST):
Protocol Registration, Patient Registration, and Eligibility Screening

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The application of computational and semantic standards is essential for information integration, system interoperability, workgroup collaboration, and the overall exploitation of significant prior investments in biomedical information resources. The ***Fully Integrated Research Standards & Technology (FIRST)*** grant being conducted at City of Hope has as its primary objective the development of an integrated extensible information management and decision support environment to facilitate all phases of clinical research. The project brings together enabling technologies such as standardized information modeling, object-oriented distributed architecture, and advanced graphic user interfaces. The ultimate goal is to develop a scalable interoperable system that could be extended to GCRCs nationwide.

This document represents a portion of our development process for the ***FIRST*** project. It consists of six components.

- ❑ Use Cases
- ❑ Block Diagrams
- ❑ Master Data Elements Table
- ❑ Coded Elements Tables
- ❑ Mock-Ups & Prototype Web Pages
- ❑ System Testing Scenario Log

This document walks the reader through the steps of Protocol Registration, Study Participant Registration and Eligibility Filtering functions of ***FIRST***, as an example of the Unified Information Architecture approach that we are taking. Each component of this document represents a critical step towards the development of a robust and extensible system.

- ❑ The sample Use Cases are a UML technique for capturing user requirements. They provide a detailed description of a function or process.
- ❑ The sample Block Diagrams are a conceptual representation of the Use Cases and use HL7RIM (reference Information Model) standard
- ❑ The sample Master Data Elements table is a technique for validating existing vocabularies or metadata repositories. It also assists in keeping track of user-required data elements.
- ❑ The sample Coded Elements are specific to the user's institution needs. However, standards are used when they are available as shown with the HL7 Race codes. There is a "harmonization of coded elements" process proposed in ***FIRST*** that is not represented in the sample document.
- ❑ The sample Mock-Up screens were developed along with the Use Cases to facilitate the communication or requirements and ideas between the sponsor and technical team. The Prototype Web Pages that were developed are attached to show the transition from concept to function.
- ❑ The sample System Testing Scenario Log represents the rigor of system testing needed to ensure a quality product. The testing is completed by a programmer \ developer, who is not part of the core development team.

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Sample Use Cases

Introduction to Use Cases

Protocol Registration

Study Participant Registration

Eligibility Filtering

Use Case Introduction

The following statements describe the contents of each Use Case Section and provide a legend for the symbols used through out the Use Cases.

WHAT CONSTITUTES A USE CASE?

It is a description of a process from beginning to end. A new use case is created if the post condition is different. An alternate course within a use case has the same post condition or may connect one use case to another use case.

USE CASE NUMBERING

Example use case number: **1.0.4a**

1. 0.4a - Represents a category the of use cases

1.0.4a – Represents the sequential number assigned to a use cases in a category

1.0.4a – Represents an alternate course in a use case and corresponds with the basic course step from which it branches

1.0.4a – Represents an attached document like an example data entry screen

USE CASE LEGEND

* next to a data item means it is a required field.

^ at the end of a basic course step means there is an alternate course.

THE DESCRIPTION SECTION OF A USE CASE

This is the function of the use case.

THE ACTOR SECTION OF A USE CASE

This is to identify all persons or systems that execute a step within a use case.

THE PRE-CONDITIONS SECTION OF A USE CASE

What must occur before a use case can be invoked.

THE BASIC COURSE SECTION OF A USE CASE

The step by step most common actions that will result in the desired post conditions.

THE POST CONDITION SECTION OF A USE CASE

The outcome of a use case.

THE ALTERNATE COURSE SECTION OF A USE CASE

Usually occurs if a decision or possible 'other' step from the basic course is needed but comes back to the same post condition of the use case or exits out of the function.

THE DATA ITEM SECTION OF A USE CASE

Detail on each data item used during a use case.

THE CODING SYSTEM SECTION OF A USE CASE

If there is a data item with a set list of possible values a code table will be present.

THE NOTES SECTION OF A USE CASE

General statements about the functions of a use case that will help in development

THE RISKS SECTION OF A USE CASE

Identified risks to the use case function

THE PRIORITY SECTION OF A USE CASE

Helps to prioritize the use case development

THE USE CASE DEPENDENCY SECTION OF A USE CASE

Lists all the use cases that are referenced within a use case to highlight relationships and possible risks if a use case is modified

THE EXAMPLE SCREENS

These are grouped with the screen shots of the prototype instead of the Use Case for this presentation. Gives visual 'feel' and 'flow' to what the end users will see. Helps with confirmation of functionality by the sponsors

Protocol Registration Use Cases

USE CASE 2.0 PROTOCOL REGISTRATION

DESCRIPTION

The protocol registrar enters a new protocol into the system

ACTOR

Protocol Registrar
System

PRE-CONDITIONS

The protocol registrar has received a protocol to register into the system. The protocol authoring is complete and the protocol is ready for submission to the review committees. Use Case 1.0 User Log-in

BASIC COURSE

1. The actor has logged into the system and indicates he/she wants to register a new protocol (**example screen # 3**)
 2. The system displays a page (**example screen # 5**) that allows the actor to register the protocol. The following information is requested
 - Site principal investigator name. (chosen from a pick list)* (**^Alternate Course 2.0.2 Add Principle Investigator or Primary Sponsor to pick list**)
 - Prefix
 - First Name
 - Last Name
 - Suffix
 - Full protocol title*
 - Primary sponsor name (chosen from an pick list)* (**^Alternate Course 2.0.2 Add Principle Investigator or Primary Sponsor to pick list**)
 - Primary sponsor protocol identification number*
 - Primary sponsor protocol version
 - Primary sponsor protocol version date
- (*means required fields)

3. The actor saves the data
4. The system checks for duplicate protocol. Match on Site PI and Sponsor name and Sponsor ID are flagged as duplicates. System does not find duplicate. (**^Alternate course 2.0.4 Possible duplicate protocol found**)
5. The system assigns a unique system identification.
6. The system assigns a protocol state of 'registered' (Use Case 8.0 – Protocol State)
7. The system displays the *FIRST* Protocol ID and registration date as confirmation to the actor of successful protocol registration (**example screen # 6**)
8. The actor chooses to 'continue to protocol abstraction'. (**See Use Case 2.3**) **OR** exits out to the menu page

POST CONDITION

Minimum protocol information is stored in the system. *FIRST* protocol ID assigned. The protocol state is 'registered'. Confirmation of protocol registration is displayed. Duplicate protocol registration is minimized.

ALTERNATE COURSE 2.0.2 ADD PRINCIPLE INVESTIGATOR OR PRIMARY SPONSOR TO PICK LIST

1. See Use Case. 5.5 Communicate with System Administrator

ALTERNATE COURSE 2.0.4 POSSIBLE DUPLICATE PROTOCOL FOUND

1. The System check for 100% match on data elements – Site PI, Sponsor Name and Sponsor Protocol ID. If all match then alert the Protocol Registrar of a possible duplicate protocol(s). If any of the three data element don't match then no alert is generated.
2. The Protocol Registrar is viewing a page with the possible duplicate protocol information and is asked to 'change registration data' or 'Exit'. (**example screen # 7**)
3. The Protocol Registrar may choose the following buttons:
 '**Change registration data**' button and continue Basic Course of this Use Case at step 2. Site PI, Sponsor Name or Sponsor ID must be changed or a duplicate warning with occur again.

OR

'**Exit**' to the main menu page (**example screen # 3**) without registering the new protocol.

DATA ITEM

Data Item	Validation Rule
Site Principal Investigator <ul style="list-style-type: none"> • Prefix • First Name • Last Name • Suffix 	Coded element, required

Full protocol title	required
Primary sponsor name	Coded element, required
Primary sponsor protocol identification number	required
Primary sponsor protocol version	none
Primary sponsor protocol version date	mm/dd/yyyy- forced format upon typing or calendar
<i>FIRST</i> Protocol ID	System assigned
<i>FIRST</i> Protocol Registration date	System date and time
Protocol State - Registered	System derived

CODING SYSTEM

Coded Element	Coding System	Note
Principal Investigator	FIRST PI	Recommend to be populated by HR system
Sponsor	FIRST Agency	Institution / agency code table
Protocol State	FIRST Protocol State	Derived, see Use Case 8.0

NOTES

1. Protocol registration data either never changes or changes infrequently.
2. The Protocol Registrar is able to exit out of the function at any time.
3. Data is not overwritten, it is saved and replaced.
4. The system will store the following information for audit purposes: user information that registered the protocol, FIRST institution that registered the protocol, date and time of activity.
5. The combination of data items that trigger a duplicate warning are: Site principle investigator name, Primary sponsor name, Primary sponsor protocol ID number.

RISKS

1. none

USE CASE DEPENDENCY

1.0 User Login

5.5 Communicate with System Administrator

8.0 Protocol State - Registered

PRIORITY ASSIGNMENT: 1

1 – critical to prototype; 2 – future development; 3 – out of grant scope

Study Participant Registration Use Cases

USE CASE 3.0 STUDY PARTICIPANT REGISTRATION

DESCRIPTION

The Study Participant registrar enters a new person into the system. A person has to be registered into the system before they can be a candidate participant, study participant or patient. A candidate participant is a person being considered for a study and may be assigned to a study to hold a slot while they are being qualified for the study. A study participant is a person that has qualified for a study and enrolled onto the study. A patient is a person that is receiving the study treatment or intervention. The term study participant will be used for person in this document for ease of reading. [Currently the use case is built for Unit of analysis – human. Unit of analysis will allow for the management of protocols that are non human, non clinical trial (future function). Unit of analysis – can be person (patient, or non-patient), Tissue (blood, marrow, tumors), Records, Genes, Proteins, etc. PI/Lab may only have access to specimen processing ID#s therefore, links between specimen & study participants are critical.]

ACTOR

Study Participant Registrar
System

PRE-CONDITIONS

The Study Participant registrar has received Study Participant information to register into the system. Use Case 1.0 User Log-in

BASIC COURSE

1. The actor has logged into the system and indicates he/she wants to register a new Study Participant (**example screen #3 – main menu page**)
2. The system displays a page (**example screen #26**) that allows the actor to register the Study Participant. The following information is requested
 - Medical Record Number
 - Institution
 - Study Participant Name
 - Prefix
 - **First name***.
 - Middle Initial
 - **Last name***
 - Suffix
 - AKA Name
 - Maiden Name
 - Current Address
 - Street Address
 - City
 - State

- Zip Code
- Home Phone
- Mobile Phone
- Work Phone
- **Date of Birth***

- **Gender***
- **Race***
- **Ethnicity***
- Birth City
- Birth Country

- Social Security Number

(*means required fields)

3. Actor clicks the 'Register person' button
 4. The system checks for duplicate Study Participant. System does not find duplicate. (^Alternate course 3.0.4 Possible duplicate Study Participant found)
 5. The system assigns a unique system identification.
 6. The system assigns a general status of 'registered' to the Study Participant
 7. The system displays the unique *FIRST* Study Participant ID and Study Participant registration date as confirmation to the actor of successful Study Participant registration (**example screen #28**)
 8. The system asks if the actor wants to continue to enter participant characteristics (**See Use Case 2.3**) **OR** exits out to the menu page.
- (^ indicates alternate course)

POST CONDITION

Minimum Study Participant information is stored in the system. *FIRST* Unique ID assigned. General Study Participant status is 'registered'. The actor is viewing a confirmation of Study Participant registration.

ALTERNATE COURSE 3.0.4

4. The System check for 100% match on data elements – First Name, Last Name, Gender, and DOB. If all match then alert the Protocol Registrar of a possible duplicate protocol(s). If any of the three data elements don't match then no alert is generated.
5. The Participant Registrar is viewing a page with the possible duplicate participant information and is asked to 'continue with registration' or 'Exit'. (**example screen # 29**)
6. The Protocol Registrar may choose the following buttons:
 'Continue with registration' button and continue Basic Course of this Use Case at step 3.
OR
 'Exit' to the main menu page (**example screen # 3**) without registering the new participant.

DATA ITEM

Data Item	Validation Rule
Unit of Analysis	Future
Medical Record Number	none
Institution	Coded element

Study Participant Name	
Prefix	Coded element
First Name	Alpha only, required
Middle Initial	Alpha only
Last Name	Alpha only, required
Suffix	Coded element
AKA Name	Alpha only
Maiden Name	Alpha only
Current Address	
Street Address	none
City	none
State	none
Zip Code	none
Home Phone	none
Mobile Phone	none
Work Phone	none
Date of Birth	Mm/dd/yyyy, forced format or calendar, required
Gender	Coded element, required
Race	HL7 standard coded element, required
Ethnicity	HL7 standard coded element, required
Birth City	Alpha only
Birth State	Alpha only
Birth Country	Alpha only
Social Security Number	Numeric only
Study Participant <i>FIRST</i> Unique ID	System assigned
Study Participant Registration date	System date
General Study	Registered, System

Participant Status	derived
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CODING SYSTEM

Coded Element	Coding System	Note
Principal Investigator	FIRST PI	Recommend to be populated by HR system
Sponsor	FIRST Agency	Institution / agency code table

NOTES

1. Study Participant registration data either never changes or changes infrequently.
2. The Study Participant Registrar is able to exit out of the function at any time.
3. Data is not overwritten, it is saved and replaced.
4. Communicate with SA is an option on all pages.

RISKS

May continue with registration without changing data. Need to flag name alert in system.

USE CASE DEPENDENCY

1.0 user login
2.3 Enter participant characteristics
30.0 Study Participant State - Registered

PRIORITY ASSIGNMENT: 1

1 – critical to prototype; 2 – future development; 3 – out of grant scope

Eligibility Filtering Use Cases

USE CASE 20.0 PROTOCOL ABSTRACTION FOR ELIGIBILITY FILTERING

DESCRIPTION

The protocol abstractor entered data about the protocols eligibility and exclusion criteria into the system.

ACTOR

Protocol Abstractor
System

PRE-CONDITIONS

Protocol is registered into the system.

BASIC COURSE

1. The actor has logged into the system (**See Use Case 1.0**), searched and selected the desired protocol (**See Use Case10.0**) (**example screen # 3**)
2. The system displays a page (**example screen # 4**) that allows the actor to select 'Eligibility Criteria' within the 'Protocol Abstraction' function.
3. The system displays the protocol abstraction – eligibility filtering criteria page (**example screen #22, #27, #23, #32**). The following information is requested about the protocols eligibility and exclusion criteria. All criteria are required. NA is used if the protocol does not specify.
 - Gender* (^**Alternate Course 8.0.3 Add a value to any of the pick lists**)
 - Minimum age and unit*
 - Maximum age and unit*
 - Functional status*
 - Minimum life expectancy*
 - Disease*
 - Measurable disease*
 - Disease status*
 - Evaluable disease*
 - Metastases*
 - Minimum tumor size*
 - Maximum tumor size*

- Significant history of disease*
- Active Diagnosis of disease*
- Treatment History –standard and or investigational therapy*

(*means required fields)

4. The actor saves the data*
5. The system returns the user to the protocol function page*

POST CONDITION

The protocol's eligibility/exclusion criteria are saved and can be used for protocol filtering and advance search functions.

ALTERNATE COURSE 20.0.3 ADD A VALUE TO ANY PICK LIST

1. See Use Case. 5.x Communicate with System Administrator

DATA ITEM – RULE

Data Item	Rule *All data items are required
Gender	Coded element
Minimum age number	
Minimum age unit	Coded element
Maximum age number	
Maximum age unit	Coded element
Functional status	Select one or more
Minimum life expectancy number	
Minimum life expectancy unit	Coded element
Disease	Coded element, select one or more
Measurable disease	Coded element
Disease status	Coded element
Evaluable disease	Coded element
Metastases	Coded element
Minimum tumor size number	
Maximum tumor size number	
Significant history of disease	
Cardiac Abnormality	Coded element
CNS Disease	Coded element
Brain Mets	Coded element

Pulmonary Abnormality	Coded element
Active Diagnosis of disease	
Cardiac Abnormality	Coded element
CNS Disease	Coded element
Brain Mets	Coded element
Pulmonary Abnormality	Coded element
Treatment History –standard	
Prior chemotherapy	Coded element
Prior hormone therapy	Coded element
Prior radiation therapy	Coded element
Prior vaccine/biological therapy	Coded element
Any prior therapy	Coded element
Treatment History –Investigational	
Prior chemotherapy	Coded element
Prior hormone therapy	Coded element
Prior radiation therapy	Coded element
Prior vaccine/biological therapy	Coded element
Any prior therapy	Coded element

CODING SYSTEM

Coded Element	Coding System	Note

NOTES/ BUSINESS RULES

1. Protocol eligibility/exclusion data either never changes or changes infrequently.
2. The Protocol Abstractor is able to exit out of the function at any time.
3. Data is not overwritten, it is saved and replaced.
4. The system will store the following information for audit purposes: user information, date and time of activity.
5. All protocol eligibility criteria are required. This will facilitate more accurate searches.

Risks

1. The eligibility filtering criteria were written for Oncology studies and need to be specified for other specialties.

USE CASE DEPENDENCY

1.0 User Login

10.0 Quick Protocol Search

5.5 Communicate with System Administrator

PRIORITY ASSIGNMENT: 1

1 – critical to prototype; 2 – future development; 3 – out of grant scope

USE CASE 21.0 PARTICIPANT CHARACTERISTICS

DESCRIPTION

The clinician enters data about the candidate participant into the system. When the protocol filtering function is invoked the system will find protocols that match the candidates data. This function is to aid the clinician in finding a study for the patient and the accrual of study participants to a study.

ACTOR

Clinician
System

PRE-CONDITIONS

Candidate participant has been registered into the system.

BASIC COURSE

1. The actor has logged into the system (**see Use Case 1.0**), searched and selected the desired candidate participant (**See Use Case 11.0) (example screen # 3)**)
2. The system displays a page (**example screen #41**) that allows the actor to select 'participant eligibility data' from the 'participant management' tasks.
3. The system then displays the participant characteristics page (**example # 33 and #35**). The following information is requested about the participant. The actor is directed that blanks are interpreted as "unknown".
 - Functional status
 - Minimum life expectancy
 - Disease* (**^Alternate Course 8.0.3 Add a value to any of the pick lists**)
 - Measurable disease
 - Disease status
 - Evaluable disease
 - Metastases
 - Tumor size
 - Significant history of disease
 - Active Diagnosis of disease
 - Treatment History –standard and or investigational therapy

(*means required fields)

4. The actor saves the data

5. The system returns the user to the protocol function page

POST CONDITION

The person's characteristic is saved and can be used for the protocol filtering functions.

ALTERNATE COURSE 21.0.3 ADD A VALUE TO ANY PICK LIST

See Use Case. 5.5 Communicate with System Administrator

DATA ITEM – RULE

Data Item	Rule *All data items are required
Gender	Display from demographics
DOB	Display from demographics, system calculates age for filtering function
Functional status	Choose one only
Minimum life expectancy number	
Minimum life expectancy unit	Coded element
Disease	Coded element, select one
Measurable disease	Coded element
Disease status	Coded element
Evaluable disease	Coded element
Metastases	Coded element
Tumor size number	
Significant history of disease	
Cardiac Abnormality	Coded element
CNS Disease	Coded element
Brain Mets	Coded element
Pulmonary Abnormality	Coded element
Active Diagnosis of disease	
Cardiac Abnormality	Coded element
CNS Disease	Coded element
Brain Mets	Coded element
Pulmonary Abnormality	Coded element
Treatment History –standard	
Prior chemotherapy	Coded element
Prior hormone therapy	Coded element

Prior radiation therapy	Coded element
Prior vaccine/biological therapy	Coded element
Any prior therapy	Coded element
Treatment History –Investigational	
Prior chemotherapy	Coded element
Prior hormone therapy	Coded element
Prior radiation therapy	Coded element
Prior vaccine/biological therapy	Coded element
Any prior therapy	Coded element

CODING SYSTEM

Coded Element	Coding System	Note

NOTES

1. Person eligibility data either never changes or changes infrequently.
2. The clinician is able to exit out of the function at any time.
3. Data is not overwritten, it is saved and replaced.
4. The system will store the following information for audit purposes: user information, date and time of activity.

RISKS

1. The eligibility filtering criteria were written for Oncology studies and need to be specified for other specialties.

USE CASE DEPENDENCY

11.0 Quick participant search

5.5 Communicate with System Administrator

PRIORITY ASSIGNMENT: 1

1 – critical to prototype; 2 – future development; 3 – out of grant scope

USE CASE 22.0 ELIGIBILITY FILTERING

DESCRIPTION

The protocol eligibility criteria have been entered and the candidate study participants characteristics have been entered. When the protocol filtering function is invoked the system will find protocols that match the candidates data. This function is to aid the clinician in finding a study for the patient and the accrual of study participants to a study. The difference between Eligibility filtering and advanced search is the identification of a candidate participant that exists in the system. Data is used that has been entered about the candidate participant and can be used for subsequent functions. The advanced search does not ask for a registered candidate and does not save any of the data.

ACTOR

Clinician
System

PRE-CONDITIONS

Candidate participant has been registered into the system (**Use Case 21.0**). Protocol eligibility criteria has been entered (**Use Case 20.0**).

BASIC COURSE

1. The actor has logged into the system (**see Use Case 1.0**), searched and selected the desired candidate participant (**See Use Case x.x (example screen # 3)**)
2. The system displays a page (**example screen #41**) that allows the actor to select 'Protocol Filtering' from the 'participant management' tasks.
3. The system finds a protocol(s) that match the candidate participants data and displays the information in a table format .
(**^Alternate Course 22.0.3 No Match Found**)
4. The table will have a horizontal scroll bar. This will allow the viewing of all eligibility criteria. Example Screen # 50, 51)
5. Clicking on the Protocol Title cell will expand the full protocol title.
6. Clicking on the Protocol ID will expand a Protocol summary window. The protocol summary is PI approved and designed to give further detail about the protocol to assist in eligibility assessment. (currently being added)

POST CONDITION

Filter results are displayed in a table that allows the clinician to view the person's data and the eligibility data for all matched protocols. This will allow the clinician to focus on the most appropriate protocol.

ALTERNATE COURSE 22.0.3 NO MATCH FOUND

1. The clinician is viewing a 'No protocol matched the candidate study participant's characteristics'.
2. The clinician may choose to 'edit the participant characteristics' (continue with Use Case 21.0) **or** exit to the 'main menu' page.

SEARCH – RULES FOR NA/PRESENT/ABSENT

	Protocol Value	Patient Value
Value	NA	Matches anything
Value	Present	Matches anything
Value	Absent	Matches NA and Absent
If the protocol value is an NA or Present, then return a match regardless of the patient's value. If the protocol value is Absent, then only return a match if the patient's value is NA or Absent.		

SEARCH – RULES FOR NA/EXCLUDES/MAY EXCLUDE

	Protocol Value	Patient Value	Result
Value	Excludes	Yes	No Match
Value	May Exclude	Yes	Match
Value	NA	Yes	Match
If the patient's value is Yes and the protocol's value is Excludes, then return a result of No Match. If the patient's value is Yes and the protocol's value is May Exclude, then return a result of Match. If the patient's value is Yes and the protocol's value is NA, then return a result of Match. IF THE PATIENT'S VALUE IS NO, THEN EVERYTHING IS A MATCH, REGARDLESS OF THE PROTOCOL VALUE.			

DISPLAY – RULES FOR FUNCTIONAL STATUS

Functional Status Value	Display
Able to carry on normal activity and to work; no special care needed	No Assist
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed	Some assist
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly	Full Assist

NOTES

1. The clinician is able to exit out of the function at any time.

2. The system will store the following information for audit purposes: user information, date and time of activity.
3. Search is set at 100% match.

Risks

1. The eligibility filtering criteria were written for Oncology studies and need to be specified for other specialties.

USE CASE DEPENDENCY

x.x quick participant search

20.0 Protocol Abstraction for Eligibility Filtering

21.0 Participant Characteristics

5.5 Communicate with System Administrator

PRIORITY ASSIGNMENT: 1

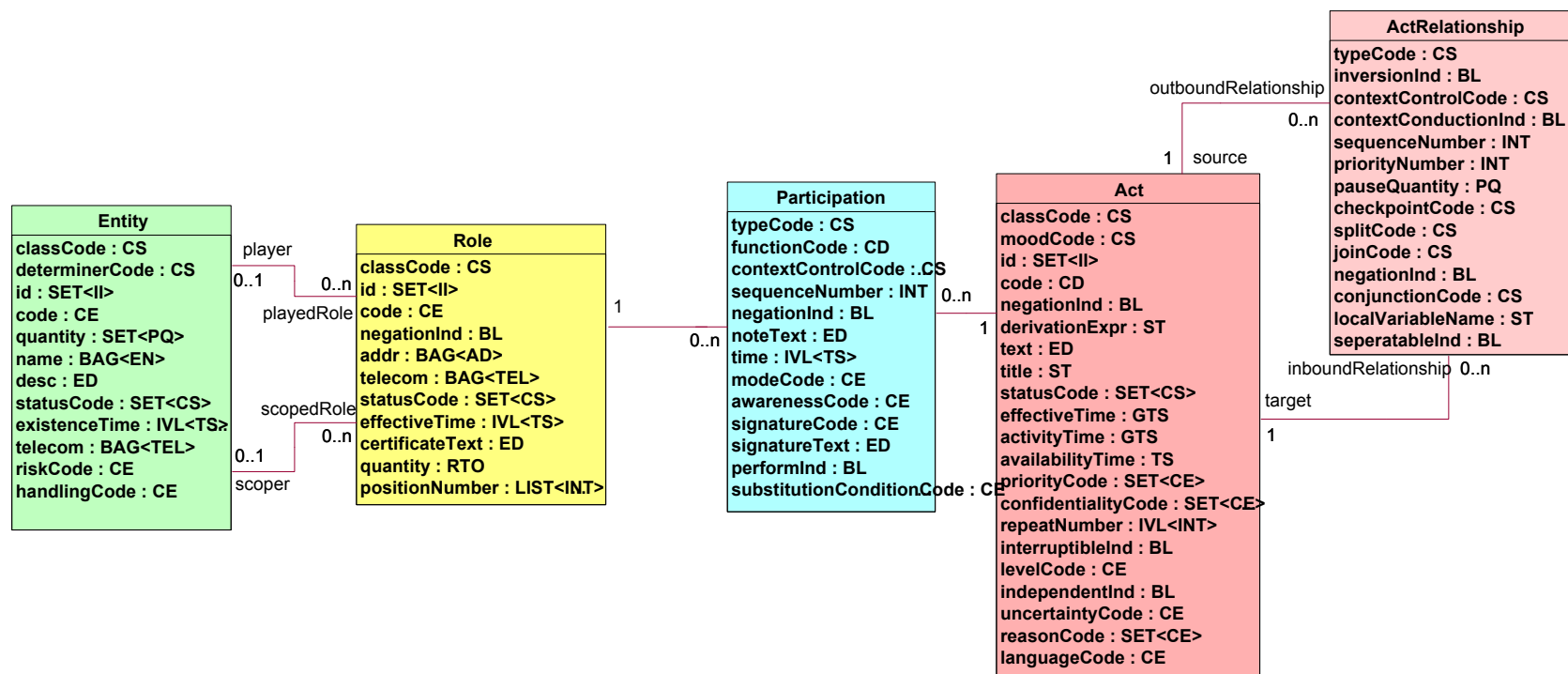
1 – critical to prototype; 2 – future development; 3 – out of grant scope

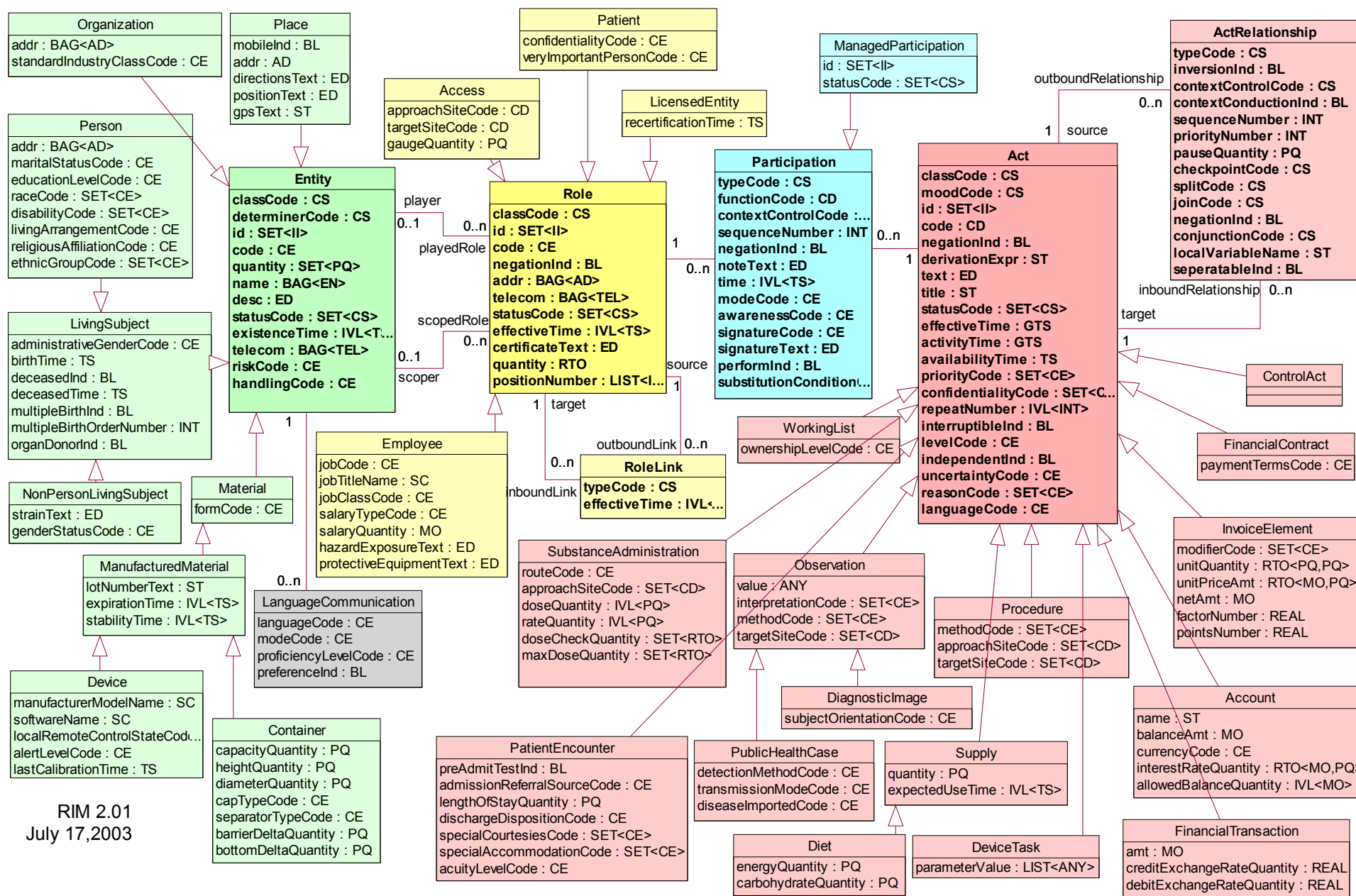
Sample Block Diagrams

Protocol Registration

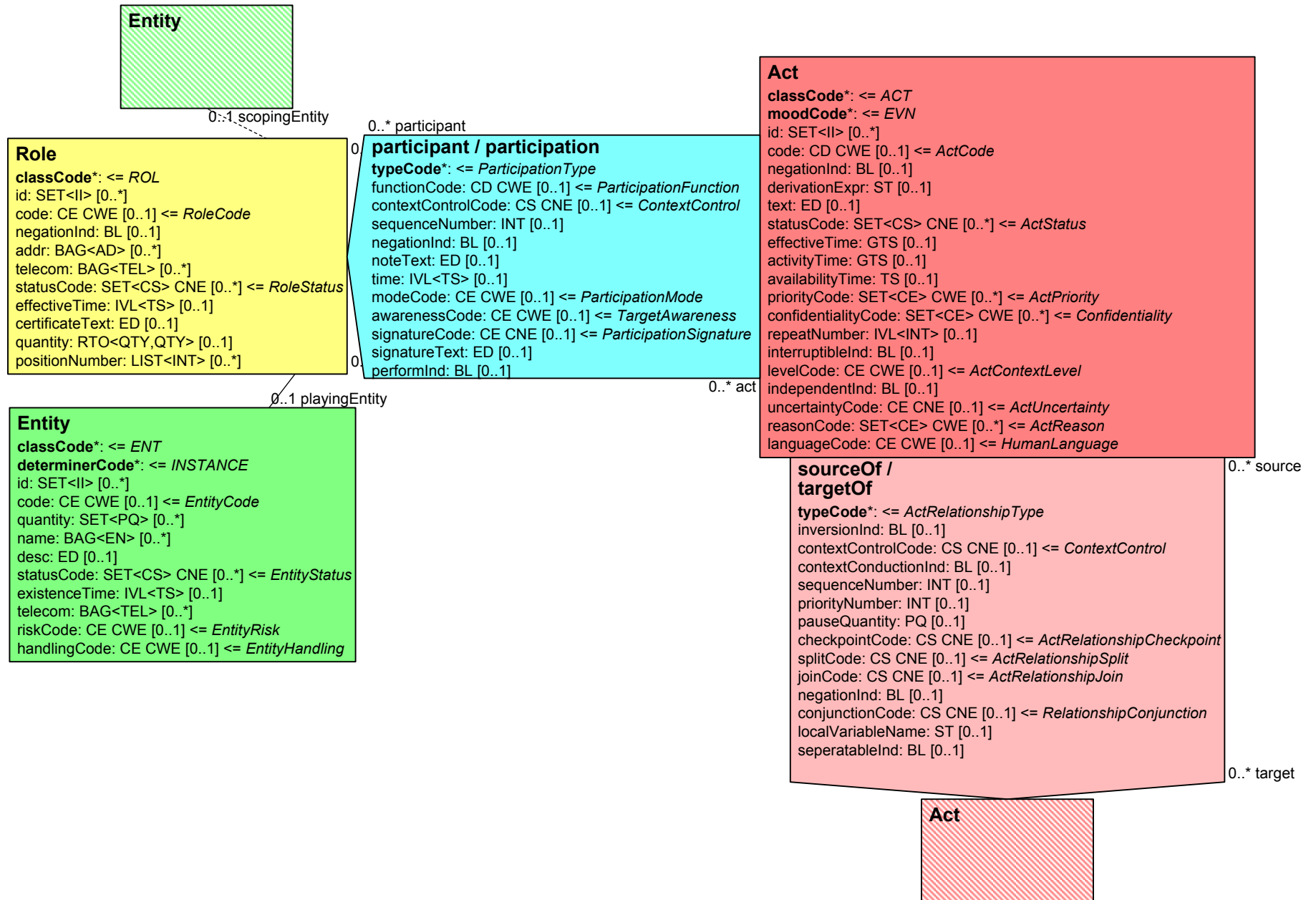
Study Participant Registration

Eligibility Filtering

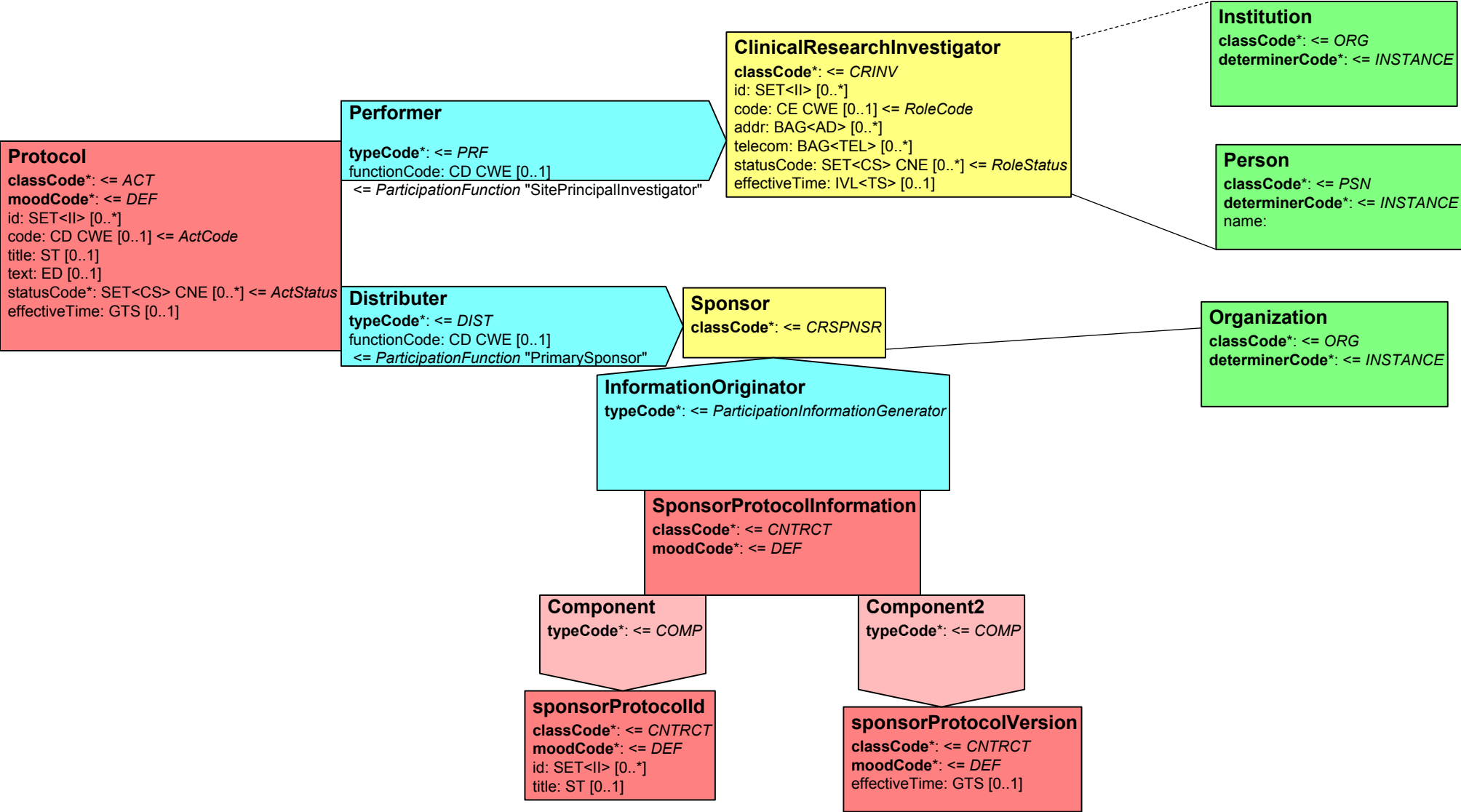




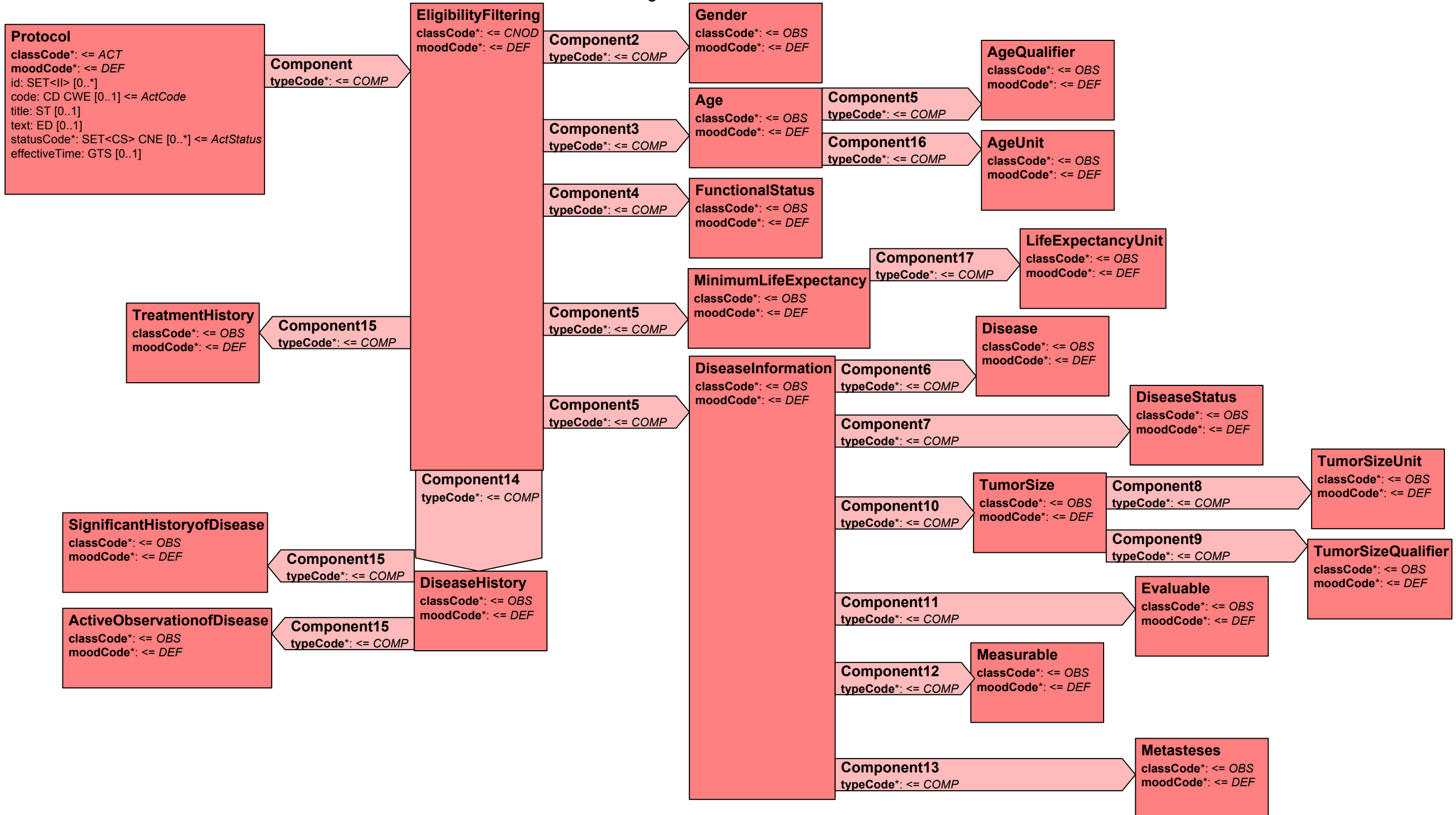
RIM-Blockdiagram - RIM



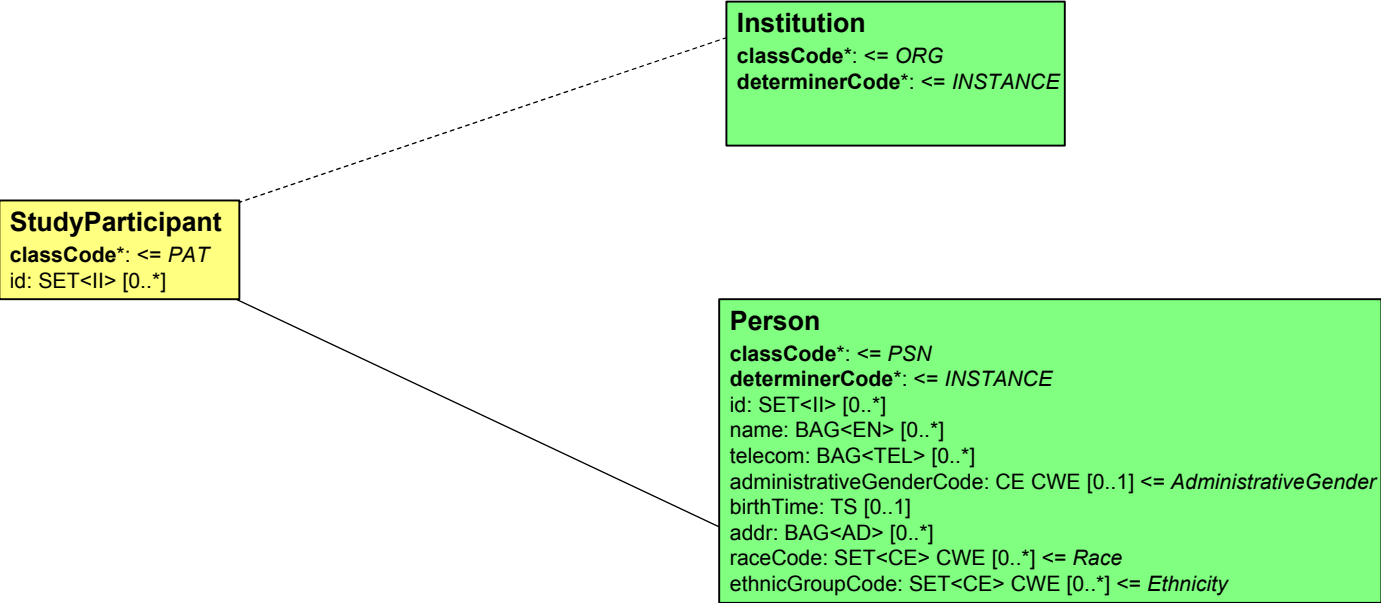
FIRST Block Diagram - Protocol Registration



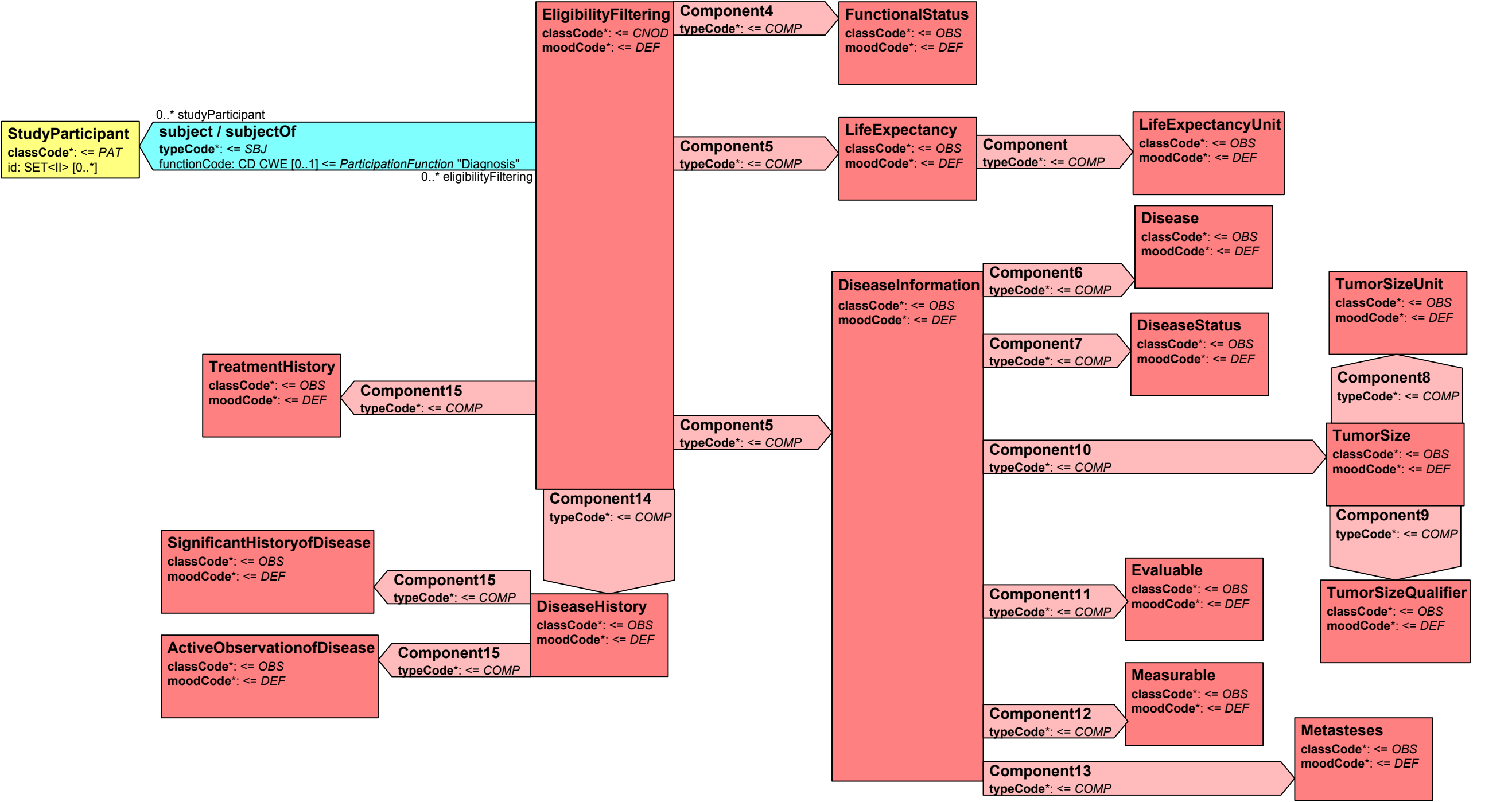
FIRST Block Diagram - Protocol Abstraction



FIRST Block Diagram - Study Participant Registration



FIRST Block Diagram - Study Participant Characteristics



Sample Master Data Elements Table

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Domain	1	LocationRef??	CDISC	A reference to the user's physical location		ST	2.8.40	NA	
User ID	1,2	LoginName	CDISC	The user's login identification		ST	2.8.40	NA	
Password	1	NA	NA	NA		ST	2.8.40	NA	
Old Password	2	NA	NA	NA		ST	2.8.40	NA	Same as password – used as check. Do not store
New password	2	NA	NA	NA		ST	2.8.40	NA	
Confirm New Password	2	NA	NA	NA		ST	2.8.40	NA	Same as password – used as check. Do not store
*Study Principal Investigator (Principal Investigator)	5,7,8,9	TRIAL_PI	RCRIM	The principal investigator responsible for the overall coordination and conduct of the trial.		XPN	2.8.51	NA	Choose from a pick list. List created in Use Case 5.x create person (protocol personnel). Recommend to use an employee export file from an HR database
<input type="checkbox"/> Prefix								NA	
<input type="checkbox"/> First Name								NA	
<input type="checkbox"/> Last Name								NA	
<input type="checkbox"/> Suffix								NA	
*Site Principal Investigator (Principal Investigator)	5,7,8,9,	INVESTIGATOR_NAME	CTEP 4.0 (released)	The name of the physician or investigator participating in a clinical trial.		XPN	2.8.51	NA	SITE_PI (RCRIM) The individual responsible for the conduct of the study at a particular site or sites and identifies the site(s).

[illegible]

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Primary Sponsor Protocol Version Date (Protocol Version Date)	5,7,8,11	VERSION_DT, VERSION_DT _CUR, or Version Date	FIRST	The month, day, and year that the most recent version of the protocol was documented.		DT	2.8.15	NA	Also Current Version Date or Prot Vers Dt (FIRST).
Primary Sponsor Protocol Status (Protocol status)	11	Sponsor Status	RCRIM	no definition		CE	2.8.3	NA	Also CURRENT_PROTOC OL_STATUS (CTEP 2.31 - draft/new) - no definition OR Current Sponsor Status, SPONSOR_ST, & Protocol Status from FIRST.
Primary Sponsor Protocol Status Date (Protocol status date)	11	SPONSOR_ST _DT	FIRST	The month, day, and year that the current sponsor status became effective.		DT	2.8.15	NA	Also Protocol Status Date, or Date of Current Sponsor Status (FIRST).
Primary Sponsor Next Review Date		REVIEW_DT	FIRST	<i>The date that the next review is scheduled.</i>		DT	2.8.15	NA	
Contact Person	16	CONTACT_PE RSON_NAME	CTEP 4.0 (appr for trial)	The name of the contact person at an institution.		XPN	2.8.51	NA	repeat contact person for 'Other Sponsor'; Review Board; Review Committee; Regulatory Agency; Multi-Center Consortium; Funding Agency; Granting Agency
Prefix	16							NA	
First Name	16							NA	
Middle Initial	16							NA	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Last Name	16							NA	
Suffix	16							NA	
Title	16							NA	
Department	16							NA	
Phone Number	16							NA	
Phone Extension	16							NA	
e-Mail Address	16							NA	
Fax Number	16							NA	
Other Sponsor									A protocol can have multiple Sponsors
Other Sponsor Name (Name)	11,16	Secondary Sponsor	FIRST	The name of a coop group or pharmaceutical company that is funding the study in addition to the primary sponsor.		ST	2.8.40	NA	Also SPONNAME_2, etc. & SPONSOR_2, etc. (FIRST). Choose from a pick list. List created in Use Case 5.x create institution (sponsor, participating center)
Other Sponsor Protocol ID (Protocol Identification)	11,16	<i>OthSponsorPr otID</i>	<i>FIRST</i>	<i>A unique identifier for the protocol assigned by a sponsor other than the primary sponsor.</i>		ST	2.8.40	NA	ID assigned by the sponsor. PROT_PARTIC_ID_NUM (CTEP 4.0 - released) - For intergroup protocols, the alphanumeric identifier assigned to the clinical study by a participating cooperative group.

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Other Sponsor Protocol Version (Protocol Version)	11	<i>OthSponsorPr otVersion</i>	<i>FIRST</i>	<i>The version assigned to the protocol by a sponsor other than the primary sponsor.</i>		ST	2.8.40	NA	Protocol version assigned by the sponsor
Other Sponsor Protocol Version Date (Protocol Version Date)	11	<i>OthSponsorVe rDate</i>	<i>FIRST</i>	<i>Date of the version assigned by a sponsor other than the primary sponsor.</i>		DT	2.8.15	NA	Date the protocol version was assigned
*FIRST Protocol ID #	3,6,7,8,9	Unique Protocol ID	FIRST	A system generated, master identifying number for the protocol that overarches all other organizations' protocol identifiers.		ST	2.8.40	NA	A sequentially assigned number (100035). Supplied by the system. Part of screen header
*Protocol Registration Date	6,7,8	<i>ProtRegisDate</i>	<i>FIRST</i>	<i>The date that the protocol was registered in the system.</i>		DT	2.8.15	NA	Supplied by the system. Part of screen header
General Protocol Status in FIRST (General Protocol Status)	8	<i>GenFIRSTProt Status</i>	<i>FIRST</i>	<i>Status of the protocol in the FIRST system. Certain rules must be met for this status to change.</i>		CE	2.8.3	NA	01 – registered See Use Case 8.0 – General Protocol Status
Other Sponsor Next Review Date		<i>OthSponsorRe vDate</i>	<i>FIRST</i>	<i>The date that the next review by an other sponsor is scheduled.</i>		DT	2.8.15	NA	
Review Committee									A protocol can have multiple review committees

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Review Committee Name (Name)		Review Board Name	FIRST	<i>The name of the institutional review body responsible for reviewing and passing judgment on the protocol.</i>		ST	2.8.40	Committee List	Choose from a pick list. List created in Use Case 5.x create institution (sponsor, participating center)
Review Committee Protocol ID (Protocol Identification)		Review Board ID	FIRST	<i>A unique identifier for the protocol assigned by a review body.</i>		ST	2.8.40	NA	ID assigned by the committee
Review Body Protocol Version (Protocol Version)		<i>RevBodyProtV ersion</i>	<i>FIRST</i>	<i>The version assigned to the protocol by the review body.</i>		ST	2.8.40	NA	Protocol version assigned by the committee
Review Committee Protocol Version Date (Protocol Version date)		<i>RevBodyVerD ate</i>	<i>FIRST</i>	<i>Date of the version assigned by the review body.</i>		DT	2.8.15	NA	Date the protocol version was assigned
Review Committee Status (Status)		IRB_STATUS	FIRST	The protocol standing at the (review body).		CE	2.8.3	NA	Also Committee Protocol Status
Review Committee Status Date (Status Date)		IRB Status Date	FIRST	The month, day, and year that the (review body) status was set.		DT	2.8.15	NA	
Review Committee Next Review Date	18	<i>RevBodyRevD ate</i>	<i>FIRST</i>	<i>The date that the next review by the committee is scheduled.</i>		DT	2.8.15	NA	
Funding Agency									A protocol can have multiple funding agencies

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Funding Agency Name (Name)	11	SPONSOR_N AME	FIRST	The name of the specific coop group or pharmaceutical company that is funding the study.		ST	2.8.40	NA	Choose from a pick list. List created in Use Case 5.x create institution (sponsor, participating center)
Funding Agency Protocol ID (Protocol Identification)	11	<i>FundAgencyPr otID</i>	<i>FIRST</i>	<i>A unique identifier for the protocol assigned by the funding agency.</i>		ST	2.8.40	NA	ID assigned by the funding agency
Funding Agency Protocol Version (Protocol Version)	11	<i>FundAgencyPr otVersion</i>	<i>FIRST</i>	<i>The version assigned to the protocol by the funding agency.</i>		ST	2.8.40	NA	Protocol version assigned by the funding agency
Funding Agency Protocol Version Date (Protocol Version Date)	11	<i>FundAgencyV erDate</i>	<i>FIRST</i>	<i>Date of the version assigned by the funding agency.</i>		DT	2.8.15	NA	Date the protocol version was assigned
Funding Agency Protocol Status	11	<i>FundAgencySt atus</i>	<i>FIRST</i>	<i>The status assigned to the protocol by the funding agency.</i>		CE	2.8.3	coded element	
Funding Agency Protocol Status date	11	<i>FundAgencySt atDate</i>	<i>FIRST</i>	<i>The date of the status assigned by the funding agency</i>		DT	2.8.15	NA	
Funding Agency Next Review Date		REVIEW_DT	FIRST	<i>The date that the next review by the funding agency is scheduled.</i>		DT	2.8.15	NA	
Regulatory Agency	11								A protocol can have multiple funding agencies
Regulatory Agency Name	11	<i>RegAgencyNa me</i>	<i>FIRST</i>	<i>The name of the regulatory agency responsible for the protocol.</i>		ST	2.8.40	NA	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Regulatory Agency Protocol ID (Protocol Identification)	11	<i>RegAgencyPro tID</i>	<i>FIRST</i>	<i>A unique identifier for this protocol assigned by the regulatory agency.</i>		ST	2.8.40	NA	
Regulatory Agency Protocol Version (Protocol Version)	11	<i>RegAgencyPro tVersion</i>	<i>FIRST</i>	<i>The version assigned to the protocol by the regulatory agency.</i>		ST	2.8.40	NA	
Regulatory Agency Protocol Version Date	11	<i>RegAgencyVer Date</i>	<i>FIRST</i>	<i>The date of the version assigned by the regulatory agency.</i>		DT	2.8.15	NA	
Regulatory Agency Protocol Status	11	<i>RegAgencyPro tStatus</i>	<i>FIRST</i>	<i>The status assigned to the protocol by the regulatory agency.</i>		CE	2.8.3	coded element	
Regulatory Agency Protocol Status date	11	<i>RegAgencySta tDate</i>	<i>FIRST</i>	<i>The date of the regulatory agency status.</i>		DT	2.8.15	NA	
Regulatory Agency Next Review Date	18	<i>RegAgencyRe vDate</i>	<i>FIRST</i>	<i>The date that the next review by the regulatory agency is scheduled.</i>		DT	2.8.15	NA	
Multi-Center Consortium									
Consortium Name	11	<i>ConsortName</i>	<i>FIRST</i>	<i>The name of the consortium involved with the protocol.</i>		ST	2.8.40	NA	
Consortium Protocol ID (Protocol Identification)	11	Consortium Number	FIRST	A unique identifier for the protocol assigned by the consortium.		ST	2.8.40	NA	
Consortium Protocol Version (Protocol Version)	11	<i>ConsortProtVe rsion</i>	<i>FIRST</i>	<i>The version assigned to the protocol by the consortium.</i>		ST	2.8.40	NA	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Consortium Protocol Version Date	11	<i>ConsortVerDate</i>	<i>FIRST</i>	<i>The date of the version assigned by the consortium.</i>		DT	2.8.15	NA	
Consortium Protocol Status	11	<i>ConsortProtStatus</i>	<i>FIRST</i>	<i>The status assigned to the protocol by the consortium.</i>		CE	2.8.3	coded element	
Consortium Protocol Status date	11	<i>ConsortStatDate</i>	<i>FIRST</i>	<i>The date of the status assigned by the consortium.</i>		DT	2.8.15	NA	
Consortium Next Review Date	18	<i>ConsortRevDate</i>	<i>FIRST</i>	<i>The date that the next review by the consortium is scheduled.</i>		DT	2.8.15	NA	
Granting Agency									
Granting Agency Name	11	<i>GrantAgencyName</i>	<i>FIRST</i>	<i>The name of the granting agency involved with the protocol.</i>		ST	2.8.40	NA	
Granting Agency Protocol ID (Protocol Identification)	11	<i>GrantAgencyProtocolID</i>	<i>FIRST</i>	<i>A unique identifier for the protocol assigned by the granting agency.</i>		ST	2.8.40	NA	
Granting Agency Protocol Version (Protocol Version)	11	<i>GrantAgencyProtocolVersion</i>	<i>FIRST</i>	<i>The version assigned to the protocol by the granting agency.</i>		ST	2.8.40	NA	
Granting Agency Protocol Version Date	11	<i>GrantAgencyVersionDate</i>	<i>FIRST</i>	<i>The date of the version assigned by the granting agency.</i>		DT	2.8.15	NA	
Granting Agency Protocol Status	11	<i>GrantAgencyProtocolStatus</i>	<i>FIRST</i>	<i>The status assigned to the protocol by the granting agency.</i>		CE	2.8.3	coded element	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Granting Agency Protocol Status date	11	GrantAgencyS tatDate	FIRST	The date of the status assigned by the granting agency.		DT	2.8.15	NA	
Granting Agency Next Review Date	18	GrantAgencyR evDate	FIRST	The date that the next review by the granting agency is scheduled.		DT	2.8.15	NA	
Protocol Personnel									choose from a pick list. List created in Use Case 5.x create person (protocol staff). Recommend to use an employee export file from an HR database
Protocol Personnel - Role (Role)	10,14	Person's Role	FIRST	The job description/title for the protocol resource.		CE	2.8.3	Protocol Personnel Role Values	
Protocol Personnel - Person's Name	10,14	CONTACT_PE RSON_NAME	CTEP 4.0 (appr for trial)	The name of a contact person at an institution.		XPN	2.8.51	NA	
Prefix	14							NA	
First Name	14							NA	
Middle Initial	14							NA	
Last Name	14							NA	
Suffix	14							NA	
Title	14							NA	
Institution	14							NA	
Department	14							NA	
Phone number	14							NA	
Phone extension	14							NA	
e-mail address	14							NA	
fax number	14							NA	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Funding Agency Number		FundAgencyNo	FIRST	The grant number from the funding agency.		ST	2.8.40	NA	
Protocol Act		EVENT_ACT	FIRST	The types of action tasks tracked for a protocol.		CE	2.8.3	Probably coded	Acts initiated, events are spontaneous
IDE Number	10,12	IDE Number	FIRST	If the protocol involves an investigational device (IDE), the investigational device number assigned by the FDA.		ST	2.8.40	NA	
IND Number	10,12	PROTNR	RCRIM	Identifies the protocol and the IND with which it is associated upon first submission of the trial. May be updated to add additional IND affiliations.		ST	2.8.40	NA	
Scientific Objectives									
Primary Study Objective	19	Main Objective	RCRIM	no definition available		ST	2.8.40	NA	
Primary Hypothesis	19	Hypothesis	RCRIM	no definition available		ST	2.8.40	NA	
Primary Endpoint(s)	19	Primary Endpoint	RCRIM	no definition available		ST	2.8.40	NA	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Treatment Arm(s)	25	ASSIGNED_T REATMENT_A RM or TX_ARM_NUM	CTEP 3.0 (appr for trial & released)	Assigned treatment arm OR the number to uniquely identify the type of treatment assigned for a clinical trial. Each trial may typically have one or more treatment arms & patients are assigned to one treatment arm		ST	2.8.40	NA	Arm Description - Description or name of the study arm OR Arm - a prespecified treatment strategy, may consist of multiple epochs & treatments (RCRIM).
Subject Strata (s)	25	Stratification	RCRIM	Subgroups for randomization		ST	2.8.40	NA	
Accrual Goals									
Protocol Target Evaluable Accrual Number	30	Subject Enrollment per Trial	RCRIM	Planned number per trial.		NM	2.8.27	NA	Targeted Accrual Global or Total Targeted Accrual Global (FIRST) - An estimate of the number of patients that should be accrued to the protocol.
Site Target Evaluable Accrual	30	Subject Enrollment per Site	RCRIM	no definition available		NM	2.8.27	NA	ACCR_TARGET (FIRST) an estimate of the # of patients at COH that should be accrued to the protocol.

[illegible]

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Subject Type	40	<i>SubjectType</i>	<i>FIRST</i>	<i>Indication as to whether the study involves human participants, medical charts, or blood/tissue samples.</i>		CE	2.8.3	Subject Type	
Study Intent	40	Global Intent	FIRST	Defines the overall goal of conducting the research as being either directed at improving treatment (therapeutic) or preventing disease, or symptoms, managing symptoms, improving quality of life, etc. (control prevention).		CE	2.8.3	Study Intent	
Time Orientation	40	Time Orientation of Study	FIRST	Defines whether the observations, interventions, and/or analyses will be conducted going forward in time (prospectively), or if only previously existing observations and data records will be analyzed (retrospective). Both is also valid.		CE	2.8.3	Time Orientation	
Interventional Sub-type (Phase)	40	Study Phase	RCRIM	The study type as described in FDA regulations.		CE	2.8.3	Interventional Sub-type	PHASE in BITS

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Interventional Study Design	40	<i>InterventStudy Design</i>	<i>FIRST</i>	<i>The schema/design of an interventional study.</i>		CE	2.8.3	Interventio nal Study Design	
Observational Study Design	40	<i>ObservatStudy Design</i>	<i>FIRST</i>	<i>The schema/design of an observational study.</i>		CE	2.8.3	Observatio nal Study Design	
Study Design		Study Design	RCRIM	Type of study schematic/experiment al design.		CE	2.8.3	Study Design	DESIGN_OF_STUDY in BITS
Treatment Involved? y/n	12	TX_INVOLVED	FIRST	A flag to indicate that the protocol involves treatment of any kind.		CE	2.8.3	NA	
Scientific Program Type		Scientific Area Code	FIRST	A code to indicate the general area of study; clinical if involving patients and basic science if at the cellular or genetic level.		CE	2.8.3	Scientific Program Type	
Multi-disciplinary? y/n	12	Multidisciplinar y Y/N	FIRST	A flag to indicate that the protocol is conducted in more than 1 COH department.		CE	2.8.3	NA	
If yes, multi-disciplinary service	12	<i>MultidiscServic e</i>	<i>FIRST</i>	<i>The different medical disciplines that are represented in the protocol's treatment plan.</i>		CE	2.8.3	Multi- disciplinary Service	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Informed consent required? y/n	12	InfConsentReq YN	FIRST	Indication as to whether the protocol requires an informed consent.		CE	2.8.3	NA	
Is this study investigator initiated? y/n	12	InvestInitiated YN	FIRST	Indication as to whether the protocol was initiated by an investigator.		CE	2.8.3	NA	
Multi-Center Trial?	12	MULTI_CTR or Multi- CenteredYN	FIRST	A flag to indicate that the protocol is conducted at more than one center.		CE	2.8.3	coded Y/N	
Affect 'Available to Accrual Status?	16,18	AvailToAccrual YN	FIRST	Indication as to whether this entity can affect the ability to accrue participant's on the study.		CE	2.8.3	coded Y/N	
Notes	14,18,16	NOTE, COMMENTS1, or COMMENTS2	CTEP 4.0 or 3.0 (draft/new)	notes		ST	2.8.40	NA	
Protocol Eligibility Criteria									Description of Participant Characteristics that will determine if a participant may be eligible for the study.
Demographics									
Gender		ProtGenderCrit	FIRST	The gender requirements of the protocol.		CE	2.8.3	coded element	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Age Minimum #		MIN_AGE	FIRST	The minimum age allowed for accrual to the protocol.		NM	2.8.27	NA	MINIMUM_AGE - LBCC v2.31 retired, Subject Age Range(s) - RCRIM
Age Maximum #		Max Age	FIRST	The maximum age allowed for accession onto the protocol.		NM	2.8.27	NA	MAXIMUM_AGE - LBCC v2.31 retired, Subject Age Range - RCRIM
Age unit		AgeMeasUnit	FIRST	<i>The unit of measurement used for age.</i>		CE	2.8.3	coded element	MeasurementUnit - CDISC
Participant Status									
General Performance Status		MIN_KPS	FIRST	The minimum KPS to qualify the patient for enrollment on this protocol.		CE	2.8.3	coded element	PERF_SCALE (FIRST)
Minimum Life Expectancy		ProtMinLifeExpect	FIRST	<i>The minimum life expectancy criteria for the protocol.</i>		NM	2.8.27	NA	
Life Expectancy Unit		LifeExpectUnit	FIRST	<i>The unit of measurement used for life expectancy.</i>		CE	2.8.3	coded element	MeasurementUnit - CDISC
Disease									
Eligible Diseases	23	ProtEligDisease	FIRST	<i>An indication of the diseases that are eligible for the protocol.</i>		CE	2.8.3	coded element	
Measurable Disease	23	ProtMeasDisease	FIRST	<i>An indication of the extent of measurable disease that is eligible for the protocol.</i>		CE	2.8.3	coded element	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Global Disease status	23	Population Disease Condition	RCRIM	Describe disease condition of the subject population, codifying the disease condition using a terminology.		CE	2.8.3	coded element	
Evaluable Disease	23	<i>ProtEvalDisease</i>	<i>FIRST</i>	<i>An indication of the diseases considered to be evaluable for the protocol.</i>		CE	2.8.3	coded element	
Metastases	23	<i>ProtMetsCrit</i>	<i>FIRST</i>	<i>An indication as to whether the presence of metastases is allowed on the protocol.</i>		CE	2.8.3	coded element	
Tumor Size # (min)	23	<i>ProtTumorMinSz</i>	<i>FIRST</i>	<i>The minimum tumor size allowed on the protocol.</i>		NM	2.8.27	NA	
Tumor Size # (max)	23	<i>ProtTumorMaxSz</i>	<i>FIRST</i>	<i>The maximum tumor size allowed on the protocol.</i>		NM	2.8.27	NA	
Tumor Size Unit	23	<i>TumorMeasUnit</i>	<i>FIRST</i>	<i>The unit of measurement used for tumor size.</i>		CE	2.8.3	coded element	MeasurementUnit - CDISC
Disease History									
Cardiac Abnormality ; Significant Hx	23	<i>ProtCardDzHxYN</i>	<i>FIRST</i>	<i>Indication as to whether a history of cardiac disease is allowed on the protocol.</i>		CE	2.8.3	coded element	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Cardiac Abnormality ; Active Diagnosis	23	ProtCardDzPr esYN	FIRST	Indication as to whether existing cardiac disease is allowed on the protocol.		CE	2.8.3	coded element	
CNS Disease; Significant History	23	ProtCNSDzHx YN	FIRST	Indication as to whether a history of CNS disease is allowed on the protocol.		CE	2.8.3	coded element	
CNS Disease; Active Diagnosis	23	ProtCNSDzPre sYN	FIRST	Indication as to whether existing CNS disease is allowed on the protocol.		CE	2.8.3	coded element	
Brain Mets; Significant History	23	ProtBrainMets HxYN	FIRST	Indication as to whether a history of brain metastases is allowed on the protocol.		CE	2.8.3	coded element	
Brain Mets; Active Diagnosis	23	ProtBrainMets PresYN	FIRST	Indication as to whether existing brain metastases is allowed on the protocol.		CE	2.8.3	coded element	
Pulmonary Abnormality; Significant History	23	ProtPulmDzHx YN	FIRST	Indication as to whether a history of pulmonary disease is allowed on the protocol.		CE	2.8.3	coded element	
Pulmonary Abnormality; Active Diagnosis	23	ProtPulmDzPr esYN	FIRST	Indication as to whether existing pulmonary disease is allowed on the protocol.		CE	2.8.3	coded element	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Treatment History									
Chemotherapy; Standard	32	ProtChemoStandardYN	FIRST	Indication as to whether prior standard chemotherapy is allowed on the protocol.		CE	2.8.3	coded element	
Chemotherapy; Investigational	32	ProtChemoInvestYN	FIRST	Indication as to whether prior investigational chemotherapy is allowed on the protocol.		CE	2.8.3	coded element	
Hormone Therapy; Standard	32	ProtHormoneStandardYN	FIRST	Indication as to whether prior standard hormone therapy is allowed on the protocol.		CE	2.8.3	coded element	
Hormone Therapy; Investigational	32	ProtHormoneInvestYN	FIRST	Indication as to whether prior investigational hormone therapy is allowed on the protocol.		CE	2.8.3	coded element	
Radiation; Standard	32	ProtRadStandardYN	FIRST	Indication as to whether prior standard radiation therapy is allowed on the protocol.		CE	2.8.3	coded element	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Radiation; Investigational	32	ProtRadInvest YN	FIRST	Indication as to whether prior investigational radiation therapy is allowed on the protocol.		CE	2.8.3	coded element	
Vaccine/Biological; Standard	32	ProtVaccBioSt andYN	FIRST	Indication as to whether prior standard vaccine/biological therapy is allowed on the protocol.		CE	2.8.3	coded element	
Vaccine/ Biological; Investigational	32	ProtVaccBioIn vestYN	FIRST	Indication as to whether prior investigational vaccine/biological therapy is allowed on the protocol.		CE	2.8.3	coded element	
Any Prior; Standard	32	ProtPriorStand YN	FIRST	Indication as to whether any prior standard therapy is allowed on the protocol.		CE	2.8.3	coded element	
Any Prior; Investigational	32	ProtPriorInvest YN	FIRST	Indication as to whether any prior investigational therapy is allowed on the protocol.		CE	2.8.3	coded element	
Protocol Forms	32	NA	NA	NA		NA	NA	NA	
Study Participant									
FIRST Person Identification Number	3,	PATUID	FIRST	Research participant number		ST	2.8.40	NA	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Demographics									
Study Participant Name	26	PT_NAME	CTEP 5.0 (released)	The current legal name of the person registered on the clinical trial.		XPN	2.8.51	NA	
Prefix	26							NA	
First Name	26							NA	
Middle Initial	26							NA	
Last Name	26							NA	
Suffix	26							NA	
AKA Name	26							NA	
Maiden Name	26	PT_MAIDEN_NAME	CTEP 3.0 (released)	The birth or family name of a patient, usually a female.				NA	
Date of Birth	26	PT_BD	CTEP 4.0 (released)	The month, day, and year on which the participant was born.		DT	2.8.15	NA	
Gender	26, 33	PT_GENDER_CAT	CTEP 6.0 (released)	The classification of the sex or gender role of the patient.		CE	2.8.3	coded element	Subject Gender (RCRIM)
Race	26	PT_RACE_CAT	CTEP 5.0 (released)	The patient's self-declared racial origination, independent of ethnic origination, using GAO approved categories.		CE	2.8.3	nested codes	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Ethnicity	26	PT_ETHN_CA T	CTEP 3.0 (released)	The patient's self-declared ethnic origination, independent of racial origination, using GAO approved categories.		CE	2.8.3	nested codes	
Birth City	26	PtBirthCity	FIRST	<i>The city in which the participant was born.</i>		ST	2.8.40	NA	PERSON_BIRTH_PL ACE (CTEP 2.31, draft/new)
Birth State	26	PtBirthState	FIRST	<i>The state in which the participant was born.</i>		CE	2.8.3	coded element	PERSON_BIRTH_PL ACE (CTEP 2.31, draft/new)
Birth Country	26	PtBirthCountry	FIRST	<i>The country in which the participant was born.</i>		ST	2.8.40	NA	PERSON_BIRTH_PL ACE (CTEP 2.31, draft/new)
Social Security Number	26	PT_SSN	CTEP 3.0 (released)	no definition		ST	2.8.40	NA	
Current Address		PtCurrAddress	FIRST	<i>The participant's complete current address.</i>		XAD	2.8.48	NA	
Street Address	26							NA	
City	26							NA	
State	26							NA	
Zip Code	26							NA	
Phone	26							NA	
Mobile Phone	26							NA	
Work Phone	26							NA	
Alternate Address		PtAltAddress	FIRST	<i>The participant's complete alternate address.</i>		XAD	2.8.48	NA	
Street Address	26							NA	
City	26							NA	
State	26							NA	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Zip Code	26							NA	
Phone	26							NA	
Mobile Phone	26							NA	
Work Phone	26							NA	
Participant Eligibility Filtering Characteristics									The act of entering patient characteristics and 'filtering' for protocol matches. This is a high level match. It is NOT full eligibility assessment. The participant can be 'hypothetical' or a FIRST registered person
Age		AGE	CTEP 4.0 (draft/new)	The age of the participant at the time of the clinical trial		NA	NA	NA	Calculated by the system
General Performance Status		K_PERF_STAT_SCALE, L_PERF_STAT_SCALE, PERF_STAT_SCALE	CTEP 2.0 (5.0 for Zubrod scale) released	The functional level of the patient based on the Karnofsky/Lansky/Lubrod performance scale.		CE	2.8.3	coded element	
Minimum Life Expectancy		LIFE_EXPECTANCY	CTEP 2.31 (draft/new)	the estimated time left before the patient's death is expected to occur. This may be in days, months, or years.		NM	2.8.27	NA	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Life Expectancy Unit Disease		LifeExpectUnit	FIRST	<i>The unit of measurement used for life expectancy.</i>		CE	2.8.3	coded element	MeasurementUnit - CDISC
Diseases		DZ_DX_CD??	CTEP 3.0 (released)	The patient's primary cancer diagnosis. Use CTEP terms and MeDRA codes (CDUS).		CE	2.8.3	coded element	PRIMARY_DIAGNOSIS_NAME (CTEP 2.31 draft/new) - the type or classification of the original cancer diagnosis.
Measurable Disease		MSRBL_DZ_P RES_IND-3	CTEP 3.0 (released)	A yes/no indicator that asks whether measurable disease is present.		CE	2.8.3	coded element	
Global Disease status		DZ_STATUS	CTEP 3.0 (released)	A field to report the status of a disease.		CE	2.8.3	coded element	
Evaluable Disease		PtEvalDisease	FIRST	<i>An indication as to whether evaluable disease is present.</i>		CE	2.8.3	coded element	
Metastases		PtDiseaseMets	FIRST	<i>An indication as to whether the participant's disease has metastasized.</i>		CE	2.8.3	coded element	
Tumor Size #		P_TUMOR_PR M_SZ_MSRMT	CTEP 4.0 (released)	The measurement of the primary tumor by the pathologist (for breast Ca use the max diameter of the invasive component; if multiple lesions, use the longest lesion).		NM	2.8.27	NA	
Tumor Size Unit		TUMOR_SZ_U OM	CTEP 3.0 (released)	Units in which the primary tumor is measured.		CE	2.8.3	coded element	MeasurementUnit - CDISC

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Disease History									
Cardiac Abnormality ; Significant Hx		<i>CardiacDzHxY N</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether the participant has a history of cardiac disease.</i>		CE	2.8.3	coded element	
Cardiac Abnormality ; Active Diagnosis		<i>CARD_DZ_PR ES_IND-2</i>	<i>CTEP 2.0 (appr for trial)</i>	<i>A yes/no indicator that asks whether a valvular disease with documented cardiac function compromise is present.</i>		CE	2.8.3	coded element	<i>HAS_THE_PT_SUFF ERED_CV_DISEASE or HAS_THE_PT_SUFF ERED_CV_2055679 (CTEP 3.0 - draft/new)</i>
CNS Disease; Significant History		<i>CNSDiseaseH xYN</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether the participant has a history of CNS disease.</i>		CE	2.8.3	coded element	
CNS Disease; Active Diagnosis		<i>CNSDiseasePr esYN</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether the participant has active CNS disease.</i>		CE	2.8.3	coded element	
Brain Mets; Significant History		<i>BrainMetsHxY N</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has a history of brain metastases.</i>		CE	2.8.3	coded element	
Brain Mets; Active Diagnosis		<i>BrainMetsPres YN</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has active brain metastases.</i>		CE	2.8.3	coded element	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Pulmonary Abnormality; Significant History		<i>PulmDiseaseH xYN</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has a history of pulmonary disease.</i>		CE	2.8.3	coded element	
Pulmonary Abnormality; Active Diagnosis		<i>PulmDiseaseP resYN</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has active pulmonary disease.</i>		CE	2.8.3	coded element	
Treatment History									
Chemotherapy; Standard		<i>PriorStandChe moYN</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has had prior standard chemotherapy.</i>		CE	2.8.3	coded element	PRIOR_CT_ADM_IN D-3 (CTEP 4.0 - released) - a yes/no indicator that asks whether the patient previously had chemotherapy as treatment for this cancer.
Chemotherapy; Investigational		<i>PriorInvestChe moYN</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has had prior investigational chemotherapy.</i>		CE	2.8.3	coded element	
Hormone Therapy; Standard		<i>PriorStandHor moneYN</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has had prior standard hormone therapy.</i>		CE	2.8.3	coded element	HORMONE_THERAP Y_IND (CTEP 2.32 - draft/new) - A yes/ no indicator to specify if the patient has received hormone therapy.

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Hormone Therapy; Investigational		<i>PriorInvestHormoneYN</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has had prior investigational hormone therapy.</i>		CE	2.8.3	coded element	
Radiation; Standard		<i>PriorStandRadYN</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has had prior standard radiation therapy.</i>		CE	2.8.3	coded element	PRIOR_RT_ADM_IN D-3 (CTEP 4.0 - released) - the yes/no indicator that asks whether the patient had previous radiation therapy as treatment for this cancer.
Radiation; Investigational		<i>PriorInvestRadYN</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has had prior investigational radiation therapy.</i>		CE	2.8.3	coded element	
Vaccine/Biological; Standard		<i>PriorStandVaccBioYN</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has had prior standard vaccine/biological therapy.</i>		CE	2.8.3	coded element	PRIOR_VACC_ADM_IND-3 (CTEP 3.0 - released) - A yes/no indicator that asks whether or not the patient has had prior vaccine therapy.
Vaccine/ Biological; Investigational		<i>PriorInvestVaccBioYN</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has had prior investigational vaccine/biological therapy.</i>		CE	2.8.3	coded element	

Data Element Label (Screen Name)	Example Screen #	Data Element Name	Source	Description	HL7 Object	HL7 Data Type	page	Code table	Note
Any Prior; Standard		<i>PriorStandTxY N</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has had any prior standard therapy.</i>		CE	2.8.3	coded element	
Any Prior; Investigational		<i>PriorInvestTxY N</i>	<i>FIRST</i>	<i>A yes/no indicator that asks whether a participant has had any prior investigational therapy.</i>		CE	2.8.3	coded element	

Sample Data Element Codes

	Study Type
1	Interventional Study
2	Observational Study

	Study Phase
1	Pilot
2	I
3	II
4	I/II
5	III
6	IV
7	NA
8	

	Multi-disciplinary? If yes, multi-disciplinary service
1	Nursing
2	Surgical Oncology
3	Clinical Pathology
4	Hematology
5	Medical Oncology
6	Clinical Social Work
7	Biotstatistics
8	Radiation Oncology

	Study Intent / Continuum Category
1	Disease Prevention
2	Disease Screening
3	Disease Treatment
4	NA
5	

	Subject Type
1	Human
2	Blood, Biopsy
3	Human/Chart
4	Any

	Committee List
1	Internal Review Board
2	Scientific Review
3	GCRC
4	
5	

	Study Design
1	Cohort
2	case-control
3	cross-sectional
4	NA
5	

	Interventional Study Type
1	Clinical Trial
3	Compassionate Use
4	Emergency Use – Single Patient

	Time Orientation
1	Prospective
2	Retrospective
3	Any
4	
5	
6	
7	
8	

	Protocol Personnel Role Values
1	Site Principal Investigator
2	Study Principal Investigator
3	Co-Investigator
4	Chair
5	Protocol Manager
6	Biostatistician
7	Protocol Nurse
8	Quality Monitor
9	Auditor

Health Level 7 - Microsoft Internet Explorer

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Links Web enabled BITS Entry Screen DBI Timetracking Schedule Viewer Compare BITS Export to SQL View.

Address http://www.hl7.org/ Go

Google Search Web 488 blocked AutoFill Options

Home

About HL7 Members Only Resources News
Events Membership Committees Jobs

Welcome Stacy! Library Standards Links Bookstore Training **News**

HL7 Standards

Data Models
Version 3.0
Version 2.5
Version 2.4
Version 2.3.1
Version 2.3

Clinical Context
Management (CCOW)
Specifications

Arden Syntax

Clinical Document
Architecture

HL7 Informative
Documents

HL7 Administrative
Documents

HL7 Implementations

3	L: (2089-1)	15798	2089-1	Mariana Islander	
3	L: (2090-9)	15799	2090-9	Marshalllese	
3	L: (2091-7)	15800	2091-7	Palauan	
3	L: (2092-5)	15801	2092-5	Carolinian	
3	L: (2093-3)	15802	2093-3	Kosraean	
3	L: (2094-1)	15803	2094-1	Pohnpeian	
3	L: (2095-8)	15804	2095-8	Saipanese	
3	L: (2096-6)	15805	2096-6	Kiribati	
3	L: (2097-4)	15806	2097-4	Chuukese	
3	L: (2098-2)	15807	2098-2	Yapese	
2	S: RacePacificIslandPolynesian (2078-4)	V15788	2078-4	Polynesian	
3	L: (2079-2)	15789	2079-2	Native Hawaiian	
3	L: (2080-0)	15790	2080-0	Samoan	
3	L: (2081-8)	15791	2081-8	Tahitian	
3	L: (2082-6)	15792	2082-6	Tongan	
3	L: (2083-4)	15793	2083-4	Tokelauan	
2	L: (2500-7)	15813	2500-7	Other Pacific Islander	Note that this term remains in the table for completeness, even though within HL7, the notion of Other code is deprecated.
1	S: RaceNativeAmerican (1002-5)	V14915	1002-5	American Indian or Alaska Native	
2	S: RaceAlaskanNative (1735-0)	V15470	1735-0	Alaska Native	
3	S: RaceAlaskanIndian (1737-6)	V15471	1737-6	Alaska Indian	
4	S: RaceAlaskanIndianAthabaskan (1739-2)	V15472	1739-2	Alaskan Athabaskan	
5	L: (1740-0)	15473	1740-0	Ahtna	
4	S: RaceSoutheastAlaskanIndian (1811-9)	V15543	1811-9	Southeast Alaska	
5	S: RaceSoutheastAlaskanIndianTlingit (1813-5)	V15544	1813-5	Tlingit-Haida	
6	L: (1814-3)	15545	1814-3	Angoon	
6	L: (1815-0)	15546	1815-0	Central Council of Tlingit and Haida Tribes	
6	L: (1816-8)	15547	1816-8	Chilkat	
6	L: (1817-6)	15548	1817-6	Chilkoot	
6	L: (1818-4)	15549	1818-4	Craig	
6	L: (1819-2)	15550	1819-2	...	

Applet fpover started

Internet

Sample Screen Mock-Ups & Prototype Web Pages

Protocol Registration

Study Participant Registration

Eligibility Filtering



Log Out

System Description

Domain:

User ID:

Password:

Funded by: NCRR Grant # 3M01 RR00043-S1

Protocol Registration
The following Web pages are from the prototype system.

The screenshot shows a Microsoft Internet Explorer window titled "First Login Page - Microsoft Internet Explorer". The address bar displays "http://stage.coh.org:8080/first/". The main content area features a login form with a black header bar that reads "Welcome to FIRST. Please login". Below this, the text "Funded by: NCRR Grant #" is displayed. The form includes a "Domain:" label with a dropdown menu showing "Any", a "Username:" label with a text input field, and a "Password:" label with a text input field. A "Login" button is positioned below the password field. At the bottom of the form, there is a link that says "Click here to communicate with the System Administrator". The status bar at the bottom of the browser window shows "Internet".

Figure 1. *FIRST* Login Page



Log Out

Welcome __(pre-fill with log-in name)___.

Select one of your assigned protocols.

[19203739](#) - (abbreviated protocol name)

[17294057](#) - (abbreviated protocol name)

OR

Select a protocol by entering:

FIRST Protocol Identification Number:

Sponsor Name:



Sponsor Protocol ID:

Version:

OR [Click here to Search for a protocol](#)

[Click here to Register a new protocol](#)

Search

OR

Select a person by entering:

FIRST Person Identification Number:

OR [Click here to Search for a person](#)

[Click here to Register a person to the system](#)

Search

OR

Other Tasks

System Administration Tasks

(only shows when SA logs in)

Sub-menu for Other Tasks

[Communicate with the System Administrator](#)

[Change your Password](#)

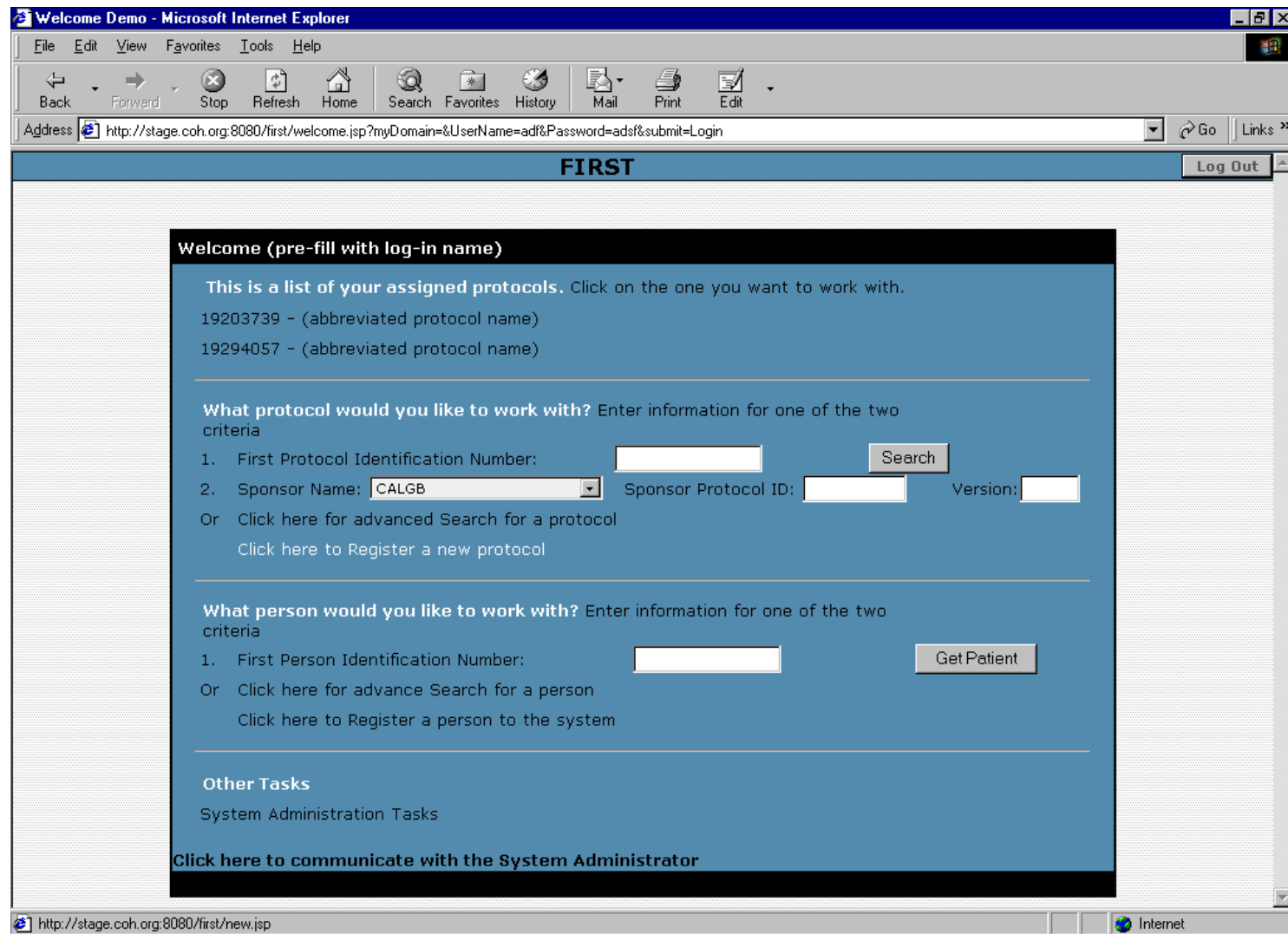


Figure 2. *FIRST* Main Menu

Example Screen # 5- Protocol Registration



Protocol Management

Participant Management

Reports


Other

Main Menu

Exit

Register Protocol

Full Protocol Title: _____

Site Principal Investigator: 

Primary Sponsor Information:

Name:  **Protocol ID Number:**

Protocol Version: **Protocol Version Date:**

Register

[Click here to communicate with the System Administrator](#)

New Protocol - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Mail Print Edit

Address <http://stage.coh.org:8080/first/new.jsp> Go Links »

Protocol Management Study Participant Management Reports Home Exit

Protocol Registration

Site PI:

Protocol Title:

Primary Sponsor Information

Name: ID Number:

Protocol Version: Date:

mm/dd/yyyy

[Click here to communicate with the System Administrator](#)

Figure 3. *FIRST* Protocol Registration

Example screen # 6- Confirmation of Protocol Registration



Protocol Management

Participant Management

Reports

Other

Main Menu

Exit

Your Protocol has been registered into **FIRSTSM**

FIRSTSM Unique Protocol ID: 100023

Registration Date: 04/29/2003

Site Principal Investigator: Michael Jensen, M.D.

Full Protocol Title: Pilot Feasibility and Safety Study of Cellular Immunotherapy for Recurrent/Refractory Malignant Glioma Using Genetically-Modified Autologous CD8⁺ T Cell Clones

Primary Sponsor Information:

Name : City of Hope

Protocol ID number: 01020

Protocol Version: 00

Protocol Version Date: 10/31/01

Protocol Status - Registered

Continue to protocol abstraction

Link to
abstraction
menu

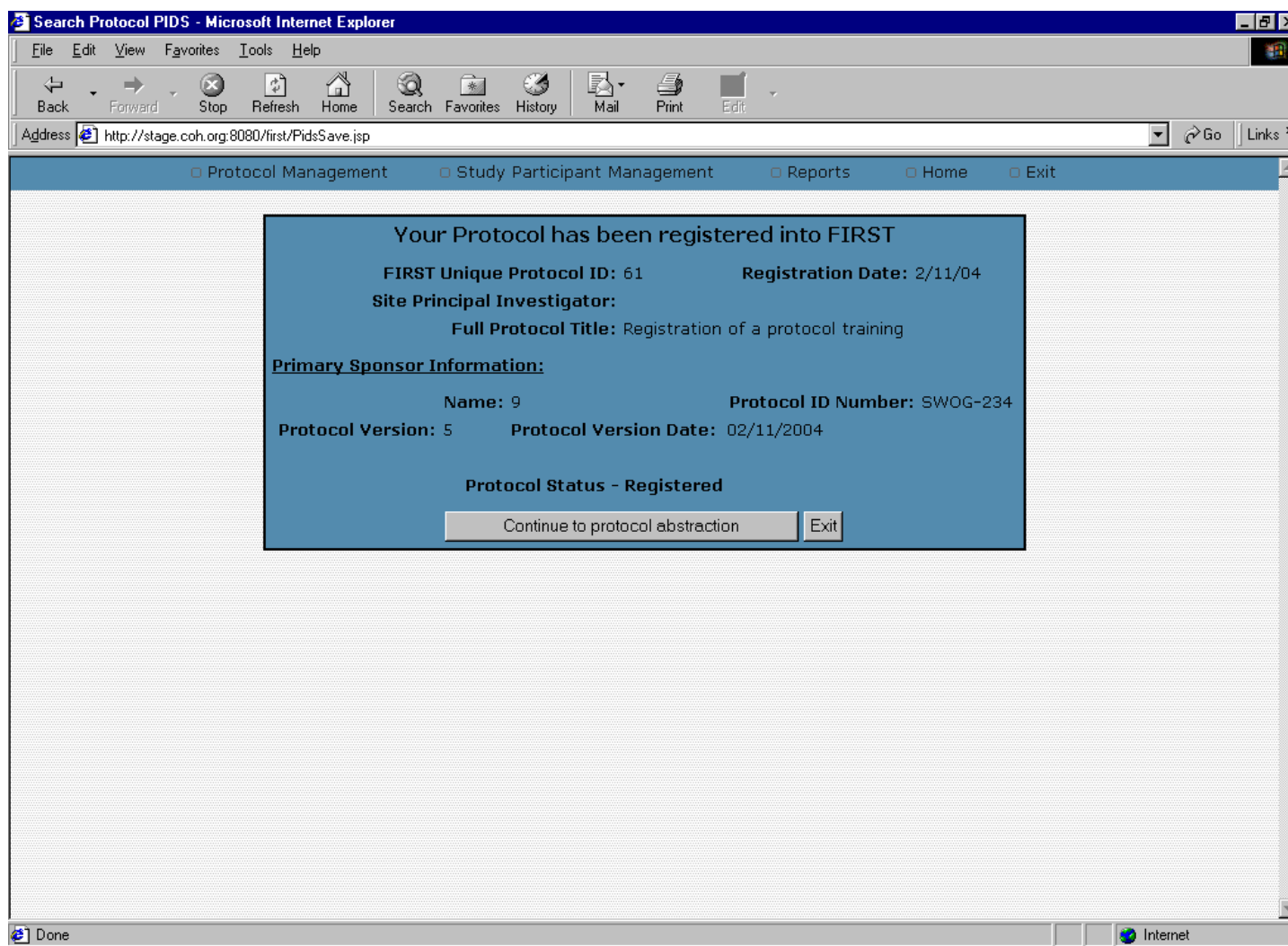


Figure 4. *FIRST* Protocol Registration Confirmation

Example Screen # 7 - Alert of Possible Duplicate Protocol



Protocol Management

Participant Management Reports

Other

Main Menu

Exit

Protocol Registration

ALERT: Possible Duplicate Protocol

The protocol below matches with the protocol you are attempting to register.

FIRST Protocol ID - 10056

Registration Date - 3/20/2002

Site Principal Investigator: Michael Jensen, M.D.

Full Protocol Title: *Pilot Feasibility and Safety Study of Cellular Immunotherapy for Recurrent/Refractory Malignant Glioma Using Genetically-Modified Autologous CD8⁺ T Cell Clones*

Primary Sponsor Information:

Name : *City of Hope*

Protocol ID number: *01020*


Protocol Version: *00*

Protocol Version Date: *10/31/01*

Proceed with Registration

Exit

Example Screen # 8 System Communication



Protocol Management Participant Management Reports Other Main Menu Exit

New Registration

Do you need to add to a pick list? Yes ☒ No ☐

Priority: Urgent ☒
Normal ☐

Type your request to the system administrator.

If you answered 'yes' to add to a pick list, remember to include what pick list or screen you are referring.

Your Name:

Contact Number or extension:

Submit Request

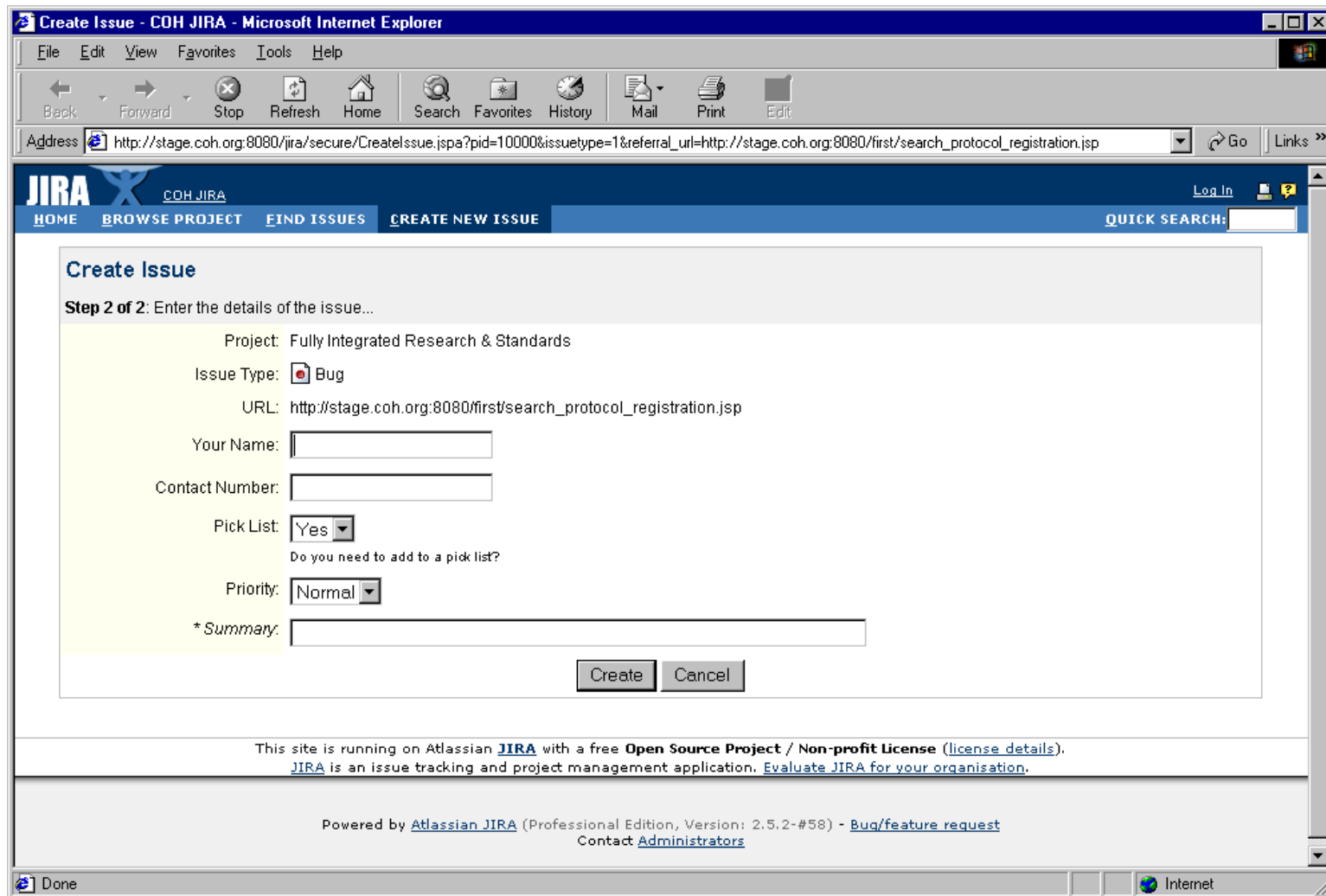



Figure 6. *FIRST* Communicate with System Administrator (using JIRA)

Example Screen # 4 - Main Menu Protocol Search Results



[Protocol](#) [Participant](#) [Reports](#) [Other](#) [Home Page](#) [Log Out](#)

Your are working with protocol: (pre-fill *FIRST* protocol ID and Title)

Protocol Abstraction

Protocol Management

Protocol Reports

Sub-menu for Protocol Abstraction

[Overview Information](#)

[Related Committees & Organizations](#)

[Protocol Personnel](#)


[Scientific Abstraction](#)

[Eligibility Criteria](#)

Study Participant list with status - Click on the persons name to access the file for this study.

[Kelly Clarkson - On Study](#)

[Tremon White - Course 1](#)



[Click here to communicate with the System Administrator](#)

See Use Case 5.x for detailed instructions for menu options and all sub-menu options

2/18/04

4



Protocol Participant R
 Protocol Registration
Protocol Abstraction
 Protocol Management T

Overview Information
 Related Entities, Committees & Organizations
 Protocol Personnel
 Scientific Abstraction
Eligibility Criteria
 Statistical Approach

Eligibility Filtering Criteria Oncologic Studies

Demographics

Gender: Minimum Maximum
 Age:*

***note:** If physiologic age is used, enter the upper limit +5 years for the maximum

Status

Check all eligible functional status descriptions:

Able to carry on normal activity and to work; no special care needed ☒

Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed ☒

Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly ☐

Minimum life expectancy: And above

[Click here to communicate with the System Administrator](#)

Example Screen # 27 - Edit/View Protocol Abstraction - Participant Characteristics for Eligibility Filtering - Disease List



Protocol Participant
Protocol Registration
Protocol Abstraction
Protocol Management

Overview Information
Committees & Organizations
Protocol Personnel
Scientific Abstraction
Eligibility Criteria
Statistical Approach

Exit

FIRSTSM Unique Protocol

This protocol is 'available' for accrual

NCI Disease List: Check all eligible

☐ Any Solid

☐ Any Hem

☐ Any Diagnosis

X

Solid Tumors:

- ☐ Anus
- ☐ Bones & Joint
- ☐ Brain & Nervous System
- ☐ Breast - Female
- ☐ Breast - Male
- ☐ Buccal Cavity & Pharynx
- ☐ Cervix
- ☐ Colon
- ☐ Corpus
- ☐ Digestive Organ, other
- ☐ Endocrine System, other

- ☐ Esophagus
- ☐ Eye and Orbit
- ☐ Genital - Female, other
- ☐ Genital - Male, other
- ☐ Ill-defined Sites
- ☐ Kaposi Sarcoma
- ☐ Kidney
- ☐ Larynx
- ☐ Liver
- ☐ Lung
- ☐ Ovary
- ☐ Pancreas

- ☐ Prostate
- ☐ Rectum
- ☐ Respiratory & intrathoracic Organs, other
- ☐ Skin Melanoma
- ☐ Skin, other
- ☐ Small Intestine
- ☐ Soft Tissue
- ☐ Stomach
- ☐ Thyroid
- ☐ Unknown Sites
- ☐ Urinary Bladder
- ☐ Urinary, other

Hematologic:

- ☐ Hematopoietic, other
- ☐ Leukemia, Lymphoid
- ☐ Leukemia, Monocytic
- ☐ Leukemia, Myeloid
- ☐ Leukemia, not otherwise specified
- ☐ Lymphoma, Hodgkin's
- ☐ Lymphoma, Non-Hodgkin's
- ☐ Mycosis Fungoides
- ☐ Multiple Myeloma

Clear

OK

[Click here to communicate with the System Administrator](#)



Protocol

Participant

Reports

Other

Main Menu

Exit

Protocol Registration
Protocol Abstraction
 Protocol Management

Overview Information
 Related Entities, Committees & Organizations
 Protocol Personnel
 Scientific Abstraction
Eligibility Criteria

Eligibility Filtering Criteria for Oncologic Studies

Disease

Click her to select eligible disease(s)

Must have measurable disease? Yes

Global disease status: Local

Must have evaluable disease? Yes

Metastases must be: Present

Tumor size: 3 cm to 10 cm

History of Disease - Conditions that could exclude the patient from being eligible.

Significant History

Active Diagnosis

Cardiac Abnormality: May Exclude

Exclude

CNS Disease: May Exclude

Exclude

Brain Mets: May Exclude

May Exclude

Pulmonary Abnormality: May Exclude

Exclude

Click here to communicate with the System Administrator

New Protocol - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Protocol Management Study Participant Management Reports Home Exit

Participant Characteristics For Eligibility Filtering

Unique Protocol ID: 46 Registration Date: 1/28/04

Study Participant Characteristics (Eligibility Criteria) for Oncologic Studies

Demographics

	Minimum	Maximum
Gender: Undifferentiated	Age* 18 Year	60 Year

Status

Check all eligible functional status descriptions:

Able to carry on normal activity and to work; no special care needed ☒

Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed ☐

Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly ☐

What is the patient's life expectancy: greater than 12 months

Disease

Primary Disease(s): Non-Hodgkin Lymphoma [Click here to add Primary Disease](#)

Global disease status: NA Must have evaluable disease? Yes

Must have measurable disease? Yes Metastases must be: N/A

tumor size: cm to cm

History of Disease

- Conditions that could exclude the patient from being eligible.

	Significant History	Active Diagnosis
Cardiac Abnormality:	May Exclude	May Exclude
CNS Disease:	Exclude	Exclude
Brain Metastasis:	May Exclude	May Exclude

Done Start CaBIGDoc - Microsoft Word New Protocol - Micros... Address Go Internet 8:26 PM

Figure 7. Abstract Eligibility Criteria from the Protocol (top of the page)



Protocol

Participant

Reports

Other

Main Menu

Exit

Protocol Registration
Protocol Abstraction
Protocol Management











Overview Information
Related Entities, Committees & Organizations
Protocol Personnel
Scientific Abstraction
Eligibility Filtering

Eligibility Filtering Criteria for Oncologic Studies

Treatment History - Conditions that could exclude the patient from being eligible.

Standard Therapy

Investigational Therapy

Prior chemotherapy:	<i>May Exclude</i> 	<i>May Exclude</i> 
Prior hormone therapy:	<i>May Exclude</i> 	<i>May Exclude</i> 
Prior radiation:	<i>May Exclude</i> 	<i>May Exclude</i> 
Prior vaccine/biological therapy:	<i>May Exclude</i> 	<i>May Exclude</i> 
Any prior therapy:	<i>May Exclude</i> 	<i>May Exclude</i> 

[Click here to communicate with the System Administrator](#)

New Protocol - Microsoft Internet Explorer

File Edit View Favorites Tools Help

What is the patient's life expectancy: greater than 12 months

Disease

Primary Disease(s): Non-Hodgkin Lymphoma [Click here to add Primary Disease](#)

Global disease status: NA Must have evaluable disease? Yes

Must have measurable disease? Yes Metastases must be: N/A

tumor size: cm to cm

History of Disease - Conditions that could exclude the patient from being eligible.

	Significant History	Active Diagnosis
Cardiac Abnormality:	May Exclude	May Exclude
CNS Disease:	Exclude	Exclude
Brain Mets:	May Exclude	May Exclude
Pulmonary Abnormality:	May Exclude	May Exclude

Treatment History - Conditions that could exclude the patient from being eligible.

	Standard Therapy	Investigational Therapy
Prior Chemotherapy :	May Exclude	May Exclude
Prior Hormone Therapy:	May Exclude	May Exclude
Prior Radiation:	May Exclude	May Exclude
Prior Vaccine/Biological Therapy:	May Exclude	May Exclude
Any Prior Therapy:	May Exclude	May Exclude

[Click here to communicate with the System Administrator](#)

Update Cancel Return to menu screen

Internet

Figure 8. Abstract Eligibility Criteria from the Protocol (bottom of the page)

Example Screen # 3- Main Menu page



Log Out

Welcome __(*pre-fill with log-in name*)__.

Select one of your assigned protocols.

[19203739 - \(*abbreviated protocol name*\)](#)

[17294057 - \(*abbreviated protocol name*\)](#)

OR

Select a protocol by entering:

FIRST Protocol Identification Number:

Sponsor Name:



Sponsor Protocol ID:

Version:

OR [Click here to Search for a protocol](#)

[Click here to Register a new protocol](#)

Search

OR

Select a person by entering:

FIRST Person Identification Number:

OR [Click here to Search for a person](#)

[Click here to Register a person to the system](#)

Search

OR

Other Tasks

System Administration Tasks

(only shows when SA logs in)

Sub-menu for Other Tasks

[Communicate with the System Administrator](#)

[Change your Password](#)

Example Screen # 26 - Person Registration to the System



Protocol **Participant** Reports Other Main Menu Exit

Registration to the System

Demographics

Unit of Analysis: *Person*

Medical Record Number:

Institution: 

Name:

Prefix: *First Name: MI: *Last Name: Suffix:

AKA Name: Maiden Name:

*Date of Birth: *Gender:  Race:  Ethnicity: 

Birth City:  Birth State: 

Birth Country:  Social Security Number:

Current Address

Address: City:  State:  Zip Code:

Phone: Mobile Phone: Work Phone:

Alternate Address

Address: City:  State:  Zip Code:

Phone: Mobile Phone: Work Phone:

[Click here to communicate with the System Administrator](#)

Register Person

Edit Demographics - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Search Favorites Media Print

Address http://stage.coh.org:8080/first/editPatient.jsp?FirstID=42 Go Links

Protocol Management Study Participant Management Reports Home Exit

Updating Patient First ID: 42

Demographics

Institution ID: 2947563640 Institution: City Of Hope

Name

Prefix: Miss First Name: Kelly M.I. M Last Name: Clarkson

Suffix: AKA Name: Maiden Name:

*Date of Birth: 12/20/1978 SELECT *Gender: Female

Race: Caucasian Ethnicity: Hispanic

Birth City: San Diego Birth State: California

Birth Country: USA Social Security Number: 527-94-2800

Current Address

Address: 3201 Mubern Lane City: Las Angeles

State: California Zip Code: 91640

Phone: 818-527-5400 Mobile Phone: 818-672-6323

Work Phone: 623-545-9100 ext 3200

Address 2

Address: 41 East Bell City: Maine

State: Arizona Zip Code: 76103

Phone: 303-634-8899 Mobile Phone:

Done Internet

Figure 9. Register Study Participant (top of page)

Edit Demographics - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Mail

Address <http://stage.coh.org:8080/first/editPatient.jsp?FirstID=42> Go Links »

First Name: M.I. Last Name:

Suffix:

AKA Name: Maiden Name:

*Date of Birth: *Gender:

Race: Ethnicity:

Birth City: Birth State:

Birth Country: Social Security Number:

Current Address

Address: City:

State: Zip Code:

Phone: Mobile Phone:

Work Phone:

Address 2

Address: City:

State: Zip Code:

Phone: Mobile Phone:

Work Phone:

Click here to communicate with the System Administrator

Done Internet

Figure 10. Register a Study Participant (bottom of page)

Example Screen # 28 - Confirmation of Person Registration to the System



Protocol **Participant** Reports Other Main Menu Exit

Registration to the System

This Person has been registered into *FIRSTSM*

***FIRSTSM* Unique Person ID:** 46586

Registration Date: 04/29/2003

Demographics

Name: Kelly M Clarkson

Date of Birth: 06/14/ 1970

Gender: Female

Medical Record Number: 294756364094

Institution: City of Hope

Study Participant Status - *Registered*

Example Screen # 29 - Alert of Possible Duplicate Person



Protocol Management

Participant Management

Reports

Other

Main Menu

Exit

New Registration

ALERT: Possible Duplicate Person

The person(s) below matches with the person you are attempting to register.
Click on the name to view more information

FIRST Person ID: 10056

Name: [Kelly A Clarkson](#)

Gender: Female

Registration Date: 3/20/2002

DOB: 05/28/1960

FIRST Person ID: 15684

Name: [Kelly P Clarkson](#)

Gender: Female

Registration Date: 7/15/2000

DOB: 05/28/1960

Continue with Registration

Exit



Home Page

Log Out

You are working with: (Person's Name)

Study Participant Management Tasks for Protocol: (prefill protocol ID and Title)

[Participant Demographics](#)

[Eligibility Filtering](#)

[Participant Eligibility Data](#)

[View Participant Roadmap](#)

[Add a Participant Event](#)

[Report an Adverse Event](#)

See Use Case 5.x for detailed instructions for menu options and all sub-menu options

List of studies and participant's status on the study. Click on the study to view/edit the participant's information for the study

#123 Ph I Combination of Anti-CEA antibody & Gemcitabine - Treatment Cycle 1	
--	--

[Click here to communicate with the System Administrator](#)



Protocol **Participant**

Demographics
Eligibility Data
 Eligibility Filter
 View Roadmap
 Add Event

Main Menu

Exit

FIRSTSM Unique Person ID: 46586

Name: Kelly M Clarkson

Patient Characteristics - Leave options blank if the data is unknown

Demographics - What is the patient's:

Gender:

Female (Prefill from demographics)

Date of Birth:

Prefill from demographics

Status - What is the patient's functional status:

Able to carry on normal activity and to work; no special care needed

☐

Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed

☒

Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly

☐

What is the patient's minimum life expectancy:

Disease - What is the patient's:

Disease?

Breast



Global disease status:

local



Is it measurable?

Yes



Is it evaluable?

Yes



Are metastases:

Present



What is the tumor size ?

3

cm

[Click here to communicate with the System Administrator](#)



Protocol **Participant**

Demographics
Eligibility Data
 Eligibility Filter
 View Roadmap
 Add Event

Main Menu

Exit

Patient Characteristics - Leave options blank if the data is unknown

History of Disease - Has the patient had any of the following?

Significant History

Active Diagnosis

Cardiac Abnormality: Yes

Yes

CNS Disease: No

No

Brain Mets: No

No

Pulmonary Abnormality: Yes

No

Treatment History - Has the patient had any of the following?

Standard Therapy

Investigational Therapy

Prior chemotherapy: Yes

No

Prior hormone therapy: Yes

No

Prior radiation therapy: Yes

No

Prior vaccine/biological therapy: No

No

Any prior therapy: Yes

No

[Click here to communicate with the System Administrator](#)

Patient Disease Characteristics - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Copy Paste

Address http://stage.coh.org:8080/first/patientDiseaseCharacteristics.jsp?FirstID=42 Go Links >>

Unique Person ID: 42 Registration Date: 1/28/04

Patient Eligibility Filtering for Oncologic Studies:

Demographics - What is the patient's:

Gender? F Date of Birth? 12/20/1978

Status

What is the patient's functional status:

Able to carry on normal activity and to work; no special care needed ☐

Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed ☐

Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly ☐

What is the patient's life expectancy: less than or equal 12 months

Disease - What is the patient's:

Disease? Multiple Myeloma Global disease status: NA

Is it measurable? Yes Is it evaluable? Yes

Are metastases: What is the tumor size? cm

History of Disease - Has the patient had any of the following?

Significant history	Active diagnosis
Cardiac Abnormality: No	No
CNS Disease:	
Brain Mets:	

Done Internet

Figure 11. Enter Study Participant Characteristics for Eligibility Filtering (top of page)

Patient Disease Characteristics - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Copy Paste

Address <http://stage.coh.org:8080/first/patientDiseaseCharacteristics.jsp?FirstID=42> Go Links >>

Disease? Global disease status:

Is it measurable? Is it evaluable?

Are metastases: What is the tumor size? cm

History of Disease - Has the patient had any of the following?

Significant history	Active diagnosis
Cardiac Abnormality: <input type="text" value="No"/>	<input type="text" value="No"/>
CNS Disease: <input type="text"/>	<input type="text"/>
Brain Mets: <input type="text"/>	<input type="text"/>
Pulmonary Abnormality: <input type="text"/>	<input type="text"/>

Treatment History - Has the patient had any of the following?

Standard Therapy	Investigational Therapy
Prior chemotherapy <input type="text"/>	<input type="text"/>
Prior hormone therapy <input type="text"/>	<input type="text"/>
Prior radiation <input type="text"/>	<input type="text"/>
Prior vaccine/biological therapy <input type="text"/>	<input type="text"/>
Any prior therapy <input type="text" value="Yes"/>	<input type="text" value="No"/>

Click here to communicate with the System Administrator

Done Internet

Figure 12. Enter Study Participant Characteristics for Eligibility Filtering (bottom of page)

Example Screen # - Protocol Filtering Search Results



Protocol Participant Reports Other Main Menu Exit

Protocol Matches for :

FIRSTSM Unique Person ID: 46586

Name: Kelly M Clarkson

	<i>Gender</i>	<i>Age</i>	<i>Status</i>	<i>Diagnosis</i>	<i>Evaluable</i>	<i>Measurable</i>	<i>Min Life Expect</i>	<i>Metastasis</i>
Pt ID:(Prefill pt ID #)	F	20	No Assist	Lymphoma	Yes	Yes	6 mo	
Protocol Information								
#113	N/A	to 18yrs	No Assist; Some Assist	Lymphoma	Yes	Yes	3 mo	N/A
#540	N/A	18yrs to 70yrs	No Assist; Some Assist	All Hem	N/A	N/A	3 mo	N/A
#700	N/A	18yrs to 65yrs	No Assist; Some Assist	All Hem	N/A	N/A	N/A	N/A
#003	N/A	18yrs to	No Assist; Some Assist	Any Cancer	N/A	N/A	N/A	N/A

Filter Summary:

15 protocols in FIRST;10 available for searching; 5 matched your query

[Click here to communicate with the System Administrator](#)

Example Screen # - Protocol Filtering Search Results



Protocol Participant Reports Other Main Menu Exit

Protocol Matches for :

FIRSTSM Unique Person ID: 46586

Name: Kelly M Clarkson

	Global Disease Status	Tumor Size	Cardiac Hx	Cardiac Active Dx	CNS Hx	CNS Active Dx
(Prefill pt name)	Local		No	No	Yes	No
Protocol Information						
#113	Local	to 10yrs	Excludes	Excludes	May Excludes	Excludes
#540	N/A	5 to	May Excludes	Excludes	May Excludes	Excludes
#700	N/A	N/A	N/A	N/A	N/A	N/A
#003	N/A	N/A	N/A	N/A	N/A	N/A

Filter Summary:

15 protocols in FIRST;10 available for searching; 5 matched your query

Example Screen # - Protocol Filtering Search Results



Protocol Participant Reports Other Main Menu Exit

Protocol Matches for :

FIRSTSM Unique Person ID: 46586

Name: Kelly M Clarkson

	<i>Brain Mets Hx</i>	<i>Brain Mets Active Dx</i>	<i>Pulmonary Hx</i>	<i>Pulmonary Active Dx</i>	<i>Prior Chemo Standard</i>	<i>Prior Chemo Investigational</i>	<i>Prior Hormone Standard</i>
(Prefill pt name)	No	No	No	No	No	No	No
Protocol Information							
#113	Excludes	Excludes	Excludes	Excludes	Excludes	Excludes	Excludes
#540	Excludes	Excludes	Excludes	Excludes	Excludes	Excludes	Excludes
#700	N/A	N/A	N/A	N/A	N/A	N/A	N/A
#003	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Filter Summary:

15 protocols in FIRST; 10 available for searching; 5 matched your query

Example Screen # - Protocol Filtering Search Results



Protocol Participant Reports Other Main Menu Exit

Protocol Matches for :

FIRSTSM Unique Person ID: 46586

Name: Kelly M Clarkson

	<i>Prior Hormone Investigational</i>	<i>Prior Radiation Standard</i>	<i>Prior Radiation Investigational</i>	<i>Vaccine / Biological Standard</i>	<i>Vaccine / Biological Investigational</i>	<i>Any Prior Therapy</i>
(Prefill pt name)	No	No	No	No	No	No
Protocol Information						
#113	Excludes	Excludes	Excludes	Excludes	Excludes	Excludes
#540	Excludes	Excludes	Excludes	Excludes	Excludes	Excludes
#700	N/A	N/A	N/A	N/A	N/A	N/A
#003	N/A	N/A	N/A	N/A	N/A	N/A

Filter Summary:

15 protocols in FIRST; 10 available for searching; 5 matched your query

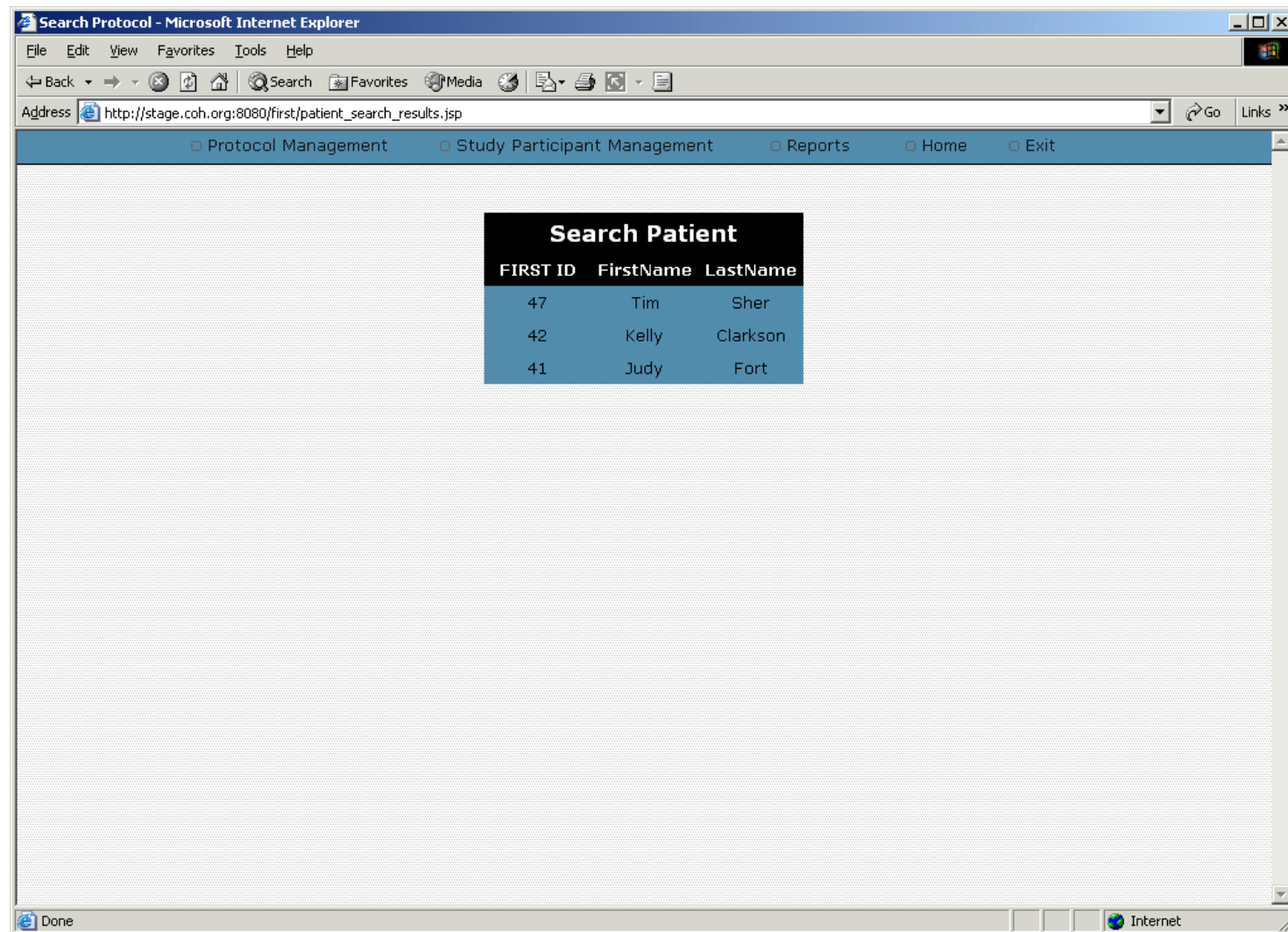


Figure 13. Select a Patient for Eligibility Filtering

Search Results - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Search Favorites Media Print

Address <http://stage.coh.org:8080/first/patientProtocolFiltering.jsp?FirstID=42> Go Links >>

Protocol Management Study Participant Management Reports Home Exit

ID	Gender	Age	Status	Diagnosis	Evaluable	Measurable	Min Life Expect	Metastasis	Global Dis
Name: Kelly M Clarkson	F	25 yrs.	Some Assist	Multiple Myeloma	Yes	Yes	less than or equal...		NA
Phase II Randomized Trial	cUN	18yrs. to 75yrs.	No Assist, Some ...	Multiple Myeloma	Yes	Yes	less than or equal...	N/A	NA

Figure 14. Eligibility Filtering Results

Search Results - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Search Favorites Media Print

Address <http://stage.coh.org:8080/first/patientProtocolFiltering.jsp?FirstID=42> Go Links >>

Protocol Management Study Participant Management Reports Home Exit

ID	Global Disease Statu	Tumor Size	Cardiac Hx	Cardiac Active Dx	CNS Hx	CNS Active Dx	Brain Mets Hx	Brain Mets Active Dx	Pulmonary I
Name: Kelly M Clarkson	NA		No	No					
Phase II Randomized Trial	cNA	N/A	May Exclude	May Exclude	Excludes	Excludes	May Exclude	May Exclude	May Exclud

Figure 15. Eligibility Filtering Results (scrolled past column 8)

Search Results - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Link

Address <http://stage.coh.org:8080/first/patientProtocolFiltering.jsp?FirstID=42> Go Links >>

Protocol Management Study Participant Management Reports Home Exit

ID	Prior Chemo Standard	Prior Chemo Investigational	Prior Hormone Standard	Prior Hormone Investigational	Prior Radiation Standard	Prior Radiation Investigational	Vaccine/Biological Standard	Vaccine/Biological Investigational	Any Prior
Name: Kelly M Clarkson									Yes
Phase II Randomized Trial	May Exclude	May Exclude	May Exclude	May Exclude	May Exclude	May Exclude	May Exclude	May Exclude	May Exclude

Figure 16. Eligibility Filtering Results (scrolled past column 16)

Sample System Testing Scenario

Eligibility Filtering

Protocol Filtering Rules Test Scenarios

Fixed Parameters Used for testing filtering rules: Unique Protocol ID 34, Patient First ID: 35

Test Scenario	Expected Result	Actual Result	Pass / Failed	Date of Test	
Protocol filtering characterizes: Gender					
1	Set protocol gender demographics to undifferentiated, patient gender to undifferentiated	Since protocol is set to undifferentiated, this protocol should display	Protocol is displayed in the result grid	Pass	1/29/04
2	Set protocol gender demographics to undifferentiated, patient gender to female	Since protocol is set to undifferentiated, this protocol should display	Protocol is displayed in the result grid	Pass	1/29/04
3	Set protocol gender demographics to undifferentiated, patient gender to male	Since protocol is set to undifferentiated, this protocol should display	Protocol is displayed in the result grid	Pass	1/29/04
4	Set protocol gender demographics to female, patient gender to undifferentiated	Since protocol is set to undifferentiated, this protocol should display	Protocol is displayed in the result grid	Pass	1/29/04
5	Set protocol gender demographics to female, patient gender set to female	This protocol should display	Protocol is displayed in the result grid	Pass	1/29/04
6	Set protocol gender demographics to female, patient gender set to male	This protocol should not display	Procotol is not displayed in the result grid	Pass	1/29/04
7	Set protocol gender demographics to male, patient gender set to undifferentiated	This protocol should display	Protocol is displayed in the result grid	Pass	1/29/04
8	Set protocol gender demographics to male, patient gender set to female	This protocol should not display	Protocol is not displayed in the result grid	Pass	1/29/04
9	Set protocol gender demographics to male, patient gender set to male	This protocol should display	Protocol is displayed in the result grid	Pass	1/29/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: <i>Min Age, Max Age</i>					
10	Set min age to empty(year), max age to empty(year), set patient DOB to any date	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
11	Set min age to empty(month), max age to empty(month), set patient DOB to any date	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04

12	Set min age to 18(year), max age to empty(year), set patient DOB to 8/14/1976	Since patient DOB is over 18 years, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04
13	Set min age to 18(month), max age to empty(year), set patient DOB to 8/14/1976	Since patient DOB is over 18 months, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04
14	Set min age to 30(year), max age to empty(year), set patient DOB to 8/14/1976	Since patient DOB is under 30 years, this protocol should not display	Protocol is displayed in result grid	Failed	1/29/04
15	Set min age to 30(month), max age to empty(year), set patient DOB to 8/14/1976	Since patient DOB is over 30 months, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04
16	Set min age to empty(year), max age to 18(year), set patient DOB to 8/14/1976	Since patient DOB is over 18 years, this protocol should not display	Protocol is displayed in result grid	Failed	1/29/04
17	Set min age to empty(year), max age to 18(month), set patient DOB to 8/14/1976	Since patient DOB is over 18 months, this protocol should not display	Protocol is displayed in result grid	Failed	1/29/04
18	Set min age to 0(year), max age to 18(year), set patient DOB to 8/14/1976	Since patient DOB is over 18 years, this protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
19	Set min age to 0(month), max age to 18(month), set patient DOB to 8/14/1976	Since patient DOB is over 18 months, this protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
20	Set min age to 30(year), max age to 60(year), set patient DOB to 8/14/1976	Since patient DOB is under 30 years, this protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
21	Set min age to 30(month), max age to 60(month), set patient DOB to 8/14/1976	Since patient DOB is over 60 months, this protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
22	Set min age to 18(year), max age to 30(month), set patient DOB to 8/14/1976	?	Protocol is not displayed in result grid	?	1/29/04
23	Set min age to 'asdf'(year), max age to empty(year), set patient DOB to 8/14/1976	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
24	Set min age to empty(year), max age to 'asdf'(year), set patient DOB to 8/14/1976	System should not take character values	500 Servlet Exception Error	Failed	2/6/04

25	Set min age to 'asdf'(year), max age to 'asdf'(year), set patient DOB to 8/14/1976	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
26	Set min age to 'asdf'(month), max age to empty(month), set patient DOB to 8/14/1976	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
27	Set min age to empty(month), max age to 'asdf'(month), set patient DOB to 8/14/1976	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
28	Set min age to 'asdf'(month), max age to 'asdf'(month), set patient DOB to 8/14/1976	System should not take character values	500 Servlet Exception Error	Failed	2/6/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: <i>Normal activity status, unable to work status, unable to care for self status</i>					
29	Set protocol normal status to uncheck, work status to uncheck, care status to uncheck, set patient filter to normal	?	Protocol is displayed in result grid	?	1/29/04
30	Set protocol normal status to uncheck, work status to uncheck, care status to uncheck, set patient filter to work	?	Protocol is displayed in result grid	?	1/29/04
31	Set protocol normal status to uncheck, work status to uncheck, care status to uncheck, set patient filter to care	?	Protocol is displayed in result grid	?	1/29/04
32	Set protocol normal status to check, work status to uncheck, care status to uncheck, set patient filter to normal	Both status matches, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04
33	Set protocol normal status to check, work status to uncheck, care status to uncheck, set patient filter to work	Status does not match, this protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
34	Set protocol normal status to check, work status to uncheck, care status to uncheck, set patient filter to care	Status does not match, this protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
35	Set protocol normal status to uncheck, work status to check, care status to uncheck, set patient filter to normal	Status does not match, this protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
36	Set protocol normal status to uncheck, work status to check, care status to uncheck, set patient filter to work	Both status matches, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04

37	Set protocol normal status to uncheck, work status to check, care status to uncheck, set patient filter to care	Status does not match, this protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
38	Set protocol normal status to uncheck, work status to uncheck, care status to check, set patient filter to normal	Status does not match, this protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
39	Set protocol normal status to uncheck, work status to uncheck, care status to check, set patient filter to work	Status does not match, this protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
40	Set protocol normal status to uncheck, work status to uncheck, care status to check, set patient filter to care	Both status matches, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04
41	Set protocol normal status to check, work status to check, care status to uncheck, set patient filter to normal	Both status matches, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04
42	Set protocol normal status to check, work status to check, care status to uncheck, set patient filter to work	Both status matches, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04
43	Set protocol normal status to check, work status to check, care status to uncheck, set patient filter to care	Status does not match, this protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
44	Set protocol normal status to uncheck, work status to check, care status to check, set patient filter to normal	Status does not match, this protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
45	Set protocol normal status to uncheck, work status to check, care status to check, set patient filter to work	Both status matches, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04
46	Set protocol normal status to uncheck, work status to check, care status to check, set patient filter to care	Both status matches, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04
47	Set protocol normal status to check, work status to uncheck, care status to check, set patient filter to normal	Both status matches, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04
48	Set protocol normal status to check, work status to uncheck, care status to check, set patient filter to work	Status does not match, this protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04

49	Set protocol normal status to check, work status to uncheck, care status to check, set patient filter to care	Both status matches, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04
50	Set protocol normal status to check, work status to check, care status to check, set patient filter to normal	Both status matches, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04
51	Set protocol normal status to check, work status to check, care status to check, set patient filter to work	Both status matches, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04
52	Set protocol normal status to check, work status to check, care status to check, set patient filter to care	Both status matches, this protocol should display	Protocol is displayed in result grid	Pass	1/29/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: <i>Life Expectancy</i>					
53	Set protocol life expectancy to greater than 12, set patient filter to empty	This protocol should display	Protocol is not displayed in result grid	Failed	1/29/04
54	Set protocol life expectancy to greater than 12, set patient filter to greater than 12	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
55	Set protocol life expectancy to greater than 12, set patient filter to less than or equal to 12	This protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
56	Set protocol life expectancy to less than or equal to 12, set patient filter to empty	This protocol should display	Protocol is not displayed in result grid	Failed	1/29/04
57	Set protocol life expectancy to less than or equal to 12, set patient filter to greater than 12	This protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
58	Set protocol life expectancy to less than or equal to 12, set patient filter to less than or equal to 12	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: <i>Disease Categories</i>					
59	Set protocol disease to Liver, set patient disease to empty	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
60	Set protocol disease to Liver, set patient disease to Liver	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04

61	Set protocol disease to Liver, set patient disease to Lung	This protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
62	Set protocol disease to Lung, Liver, set patient disease to empty	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
63	Set protocol disease to Lung, Liver, set patient disease to Liver	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
64	Set protocol disease to Lung, Liver, set patient disease to Lung	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
65	Set protocol disease to Lung, Liver, set patient disease to Kidney	This protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: <i>Global Disease Status</i>					
66	Set protocol status to Local, set patient to Local	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
67	Set protocol status to Local, set patient to Advanced	This protocol should not display	Protocol is displayed in result grid	Pass	1/29/04
68	Set protocol status to Local, set patient to N/A	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
69	Set protocol status to Advanced, set patient to Local	This protocol should not display	Protocol is displayed in result grid	Pass	1/29/04
70	Set protocol status to Advanced, set patient to Advanced	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
71	Set protocol status to Advanced, set patient to N/A	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
72	Set protocol status to N/A, set patient to Local	This protocol should display	Protocol is not displayed in result grid	Failed	1/29/04
73	Set protocol status to N/A, set patient to Advanced	This protocol should display	Protocol is not displayed in result grid	Failed	1/29/04
74	Set protocol status to N/A, set patient to N/A	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: <i>Is it measurable?</i>					
75	Set protocol status to Yes, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04

76	Set protocol status to Yes, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
77	Set protocol status to Yes, set patient to No	This protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
78	Set protocol status to No, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
79	Set protocol status to No, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
80	Set protocol status to No, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: <i>Is it evaluable?</i>					
81	Set protocol status to Yes, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
82	Set protocol status to Yes, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
83	Set protocol status to Yes, set patient to No	This protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
84	Set protocol status to No, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04
85	Set protocol status to No, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	1/29/04
86	Set protocol status to No, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	1/29/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: <i>Is it metastases?</i>					
87	Set protocol status to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
88	Set protocol status to N/A, set patient to N/A	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
89	Set protocol status to N/A, set patient to Absent	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
90	Set protocol status to N/A, set patient to Present	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

91	Set protocol status to Absent, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
92	Set protocol status to Absent, set patient to N/A	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
93	Set protocol status to Absent, set patient to Absent	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
94	Set protocol status to Absent, set patient to Present	This protocol should not display	Protocol is displayed in result grid	Failed	2/2/04
95	Set protocol status to Present, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
96	Set protocol status to Present, set patient to N/A	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
97	Set protocol status to Present, set patient to Absent	This protocol should display	Protocol is not displayed in result grid	Failed	2/2/04
98	Set protocol status to Present, set patient to Present	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: <i>Is it measurable?</i>, tumor size range					
99	Set protocol status to No, tumor min size to empty, tumor max size to empty, set patient tumor size to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
100	Set protocol status to No, tumor min size to empty, tumor max size to empty, set patient tumor size to 5	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
101	Set protocol status to No, tumor min size to 5, tumor max size to empty, set patient tumor size to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
102	Set protocol status to No, tumor min size to 5, tumor max size to empty, set patient tumor size to 0	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
103	Set protocol status to No, tumor min size to 5, tumor max size to empty, set patient tumor size to 3	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
104	Set protocol status to No, tumor min size to 5, tumor max size to empty, set patient tumor size to 5	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

105	Set protocol status to No, tumor min size to 5, tumor max size to empty, set patient tumor size to 10	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
106	Set protocol status to No, tumor min size to empty, tumor max size to 5, set patient tumor size to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
107	Set protocol status to No, tumor min size to empty, tumor max size to 5, set patient tumor size to 0	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
108	Set protocol status to No, tumor min size to empty, tumor max size to 5, set patient tumor size to 5	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
109	Set protocol status to No, tumor min size to empty, tumor max size to 5, set patient tumor size to 10	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
110	Set protocol status to No, tumor min size to 3, tumor max size to 5, set patient tumor size to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
111	Set protocol status to No, tumor min size to 3, tumor max size to 5, set patient tumor size to 0	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
112	Set protocol status to No, tumor min size to 3, tumor max size to 5, set patient tumor size to 1	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
113	Set protocol status to No, tumor min size to 3, tumor max size to 5, set patient tumor size to 4	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
114	Set protocol status to No, tumor min size to 3, tumor max size to 5, set patient tumor size to 6	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
115	Set protocol status to No, tumor min size to 'asdf', tumor max size to empty, set patient tumor size to empty	System should not take character values	Protocol is displayed in result grid	?	2/6/04
116	Set protocol status to No, tumor min size to 'asdf', tumor max size to empty, set patient tumor size to 0	System should not take character values	Protocol is displayed in result grid	?	2/6/04

117	Set protocol status to No, tumor min size to 'asdf', tumor max size to empty, set patient tumor size to 5	System should not take character values	Protocol is displayed in result grid	?	2/6/04
118	Set protocol status to No, tumor min size to 'asdf', tumor max size to empty, set patient tumor size to 'asdf'	System should not take character values	Protocol is displayed in result grid	?	2/6/04
119	Set protocol status to No, tumor min size to empty, tumor max size to 'asdf', set patient tumor size to empty	System should not take character values	Protocol is displayed in result grid	?	2/6/04
120	Set protocol status to No, tumor min size to empty, tumor max size to 'asdf', set patient tumor size to 0	System should not take character values	Protocol is displayed in result grid	?	2/6/04
121	Set protocol status to No, tumor min size to empty, tumor max size to 'asdf', set patient tumor size to 5	System should not take character values	Protocol is displayed in result grid	?	2/6/04
122	Set protocol status to No, tumor min size to empty, tumor max size to 'asdf', set patient tumor size to 'asdf'	System should not take character values	Protocol is displayed in result grid	?	2/6/04
123	Set protocol status to No, tumor min size to 'asdf', tumor max size to 'asdf', set patient tumor size to empty	System should not take character values	Protocol is displayed in result grid	?	2/6/04
124	Set protocol status to No, tumor min size to 'asdf', tumor max size to 'asdf', set patient tumor size to 0	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
125	Set protocol status to No, tumor min size to 'asdf', tumor max size to 'asdf', set patient tumor size to 5	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
126	Set protocol status to No, tumor min size to 'asdf', tumor max size to 'asdf', set patient tumor size to 'asdf'	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
127	Set protocol status to No, tumor min size to 3, tumor max size to 'asdf', set patient tumor size to empty	System should not take character values	Protocol is displayed in result grid	?	2/6/04
128	Set protocol status to No, tumor min size to 3, tumor max size to 'asdf', set patient tumor size to 0	System should not take character values	500 Servlet Exception Error	Failed	2/6/04

129	Set protocol status to No, tumor min size to 3, tumor max size to 'asdf', set patient tumor size to 5	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
130	Set protocol status to No, tumor min size to 3, tumor max size to 'asdf', set patient tumor size to 'asdf'	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
131	Set protocol status to No, tumor min size to 'asdf', tumor max size to 3, set patient tumor size to empty	System should not take character values	Protocol is displayed in result grid	?	2/6/04
132	Set protocol status to No, tumor min size to 'asdf', tumor max size to 3, set patient tumor size to 0	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
133	Set protocol status to No, tumor min size to 'asdf', tumor max size to 3, set patient tumor size to 5	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
134	Set protocol status to No, tumor min size to 'asdf', tumor max size to 3, set patient tumor size to 'asdf'	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
135	Set protocol status to Yes, tumor min size to empty, tumor max size to empty, set patient tumor size to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
136	Set protocol status to Yes, tumor min size to empty, tumor max size to empty, set patient tumor size to 5	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
137	Set protocol status to Yes, tumor min size to 5, tumor max size to empty, set patient tumor size to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
138	Set protocol status to Yes, tumor min size to 5, tumor max size to empty, set patient tumor size to 0	This protocol should not display	Protocol is displayed in result grid	Failed	2/2/04
139	Set protocol status to Yes, tumor min size to 5, tumor max size to empty, set patient tumor size to 3	This protocol should not display	Protocol is displayed in result grid	Failed	2/2/04
140	Set protocol status to Yes, tumor min size to 5, tumor max size to empty, set patient tumor size to 5	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

141	Set protocol status to Yes, tumor min size to 5, tumor max size to empty, set patient tumor size to 10	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
142	Set protocol status to Yes, tumor min size to empty, tumor max size to 5, set patient tumor size to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
143	Set protocol status to Yes, tumor min size to empty, tumor max size to 5, set patient tumor size to 0	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
144	Set protocol status to Yes, tumor min size to empty, tumor max size to 5, set patient tumor size to 5	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
145	Set protocol status to Yes, tumor min size to empty, tumor max size to 5, set patient tumor size to 10	This protocol should not display	Protocol is displayed in result grid	Failed	2/2/04
146	Set protocol status to Yes, tumor min size to 3, tumor max size to 5, set patient tumor size to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
147	Set protocol status to Yes, tumor min size to 3, tumor max size to 5, set patient tumor size to 0	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
148	Set protocol status to Yes, tumor min size to 3, tumor max size to 5, set patient tumor size to 1	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
149	Set protocol status to Yes, tumor min size to 3, tumor max size to 5, set patient tumor size to 4	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
150	Set protocol status to Yes, tumor min size to 3, tumor max size to 5, set patient tumor size to 6	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
151	Set protocol status to Yes, tumor min size to 'asdf', tumor max size to empty, set patient tumor size to empty	System should not take character values	Protocol is displayed in result grid	?	2/6/04
152	Set protocol status to Yes, tumor min size to 'asdf', tumor max size to empty, set patient tumor size to 0	System should not take character values	Protocol is displayed in result grid	?	2/6/04

153	Set protocol status to Yes, tumor min size to 'asdf', tumor max size to empty, set patient tumor size to 5	System should not take character values	Protocol is displayed in result grid	?	2/6/04
154	Set protocol status to Yes, tumor min size to 'asdf', tumor max size to empty, set patient tumor size to 'asdf'	System should not take character values	Protocol is displayed in result grid	?	2/6/04
155	Set protocol status to Yes, tumor min size to empty, tumor max size to 'asdf', set patient tumor size to empty	System should not take character values	Protocol is displayed in result grid	?	2/6/04
156	Set protocol status to Yes, tumor min size to empty, tumor max size to 'asdf', set patient tumor size to 0	System should not take character values	Protocol is displayed in result grid	?	2/6/04
157	Set protocol status to Yes, tumor min size to empty, tumor max size to 'asdf', set patient tumor size to 5	System should not take character values	Protocol is displayed in result grid	?	2/6/04
158	Set protocol status to Yes, tumor min size to empty, tumor max size to 'asdf', set patient tumor size to 'asdf'	System should not take character values	Protocol is displayed in result grid	?	2/6/04
159	Set protocol status to Yes, tumor min size to 'asdf', tumor max size to 'asdf', set patient tumor size to empty	System should not take character values	Protocol is displayed in result grid	?	2/6/04
160	Set protocol status to Yes, tumor min size to 'asdf', tumor max size to 'asdf', set patient tumor size to 0	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
161	Set protocol status to Yes, tumor min size to 'asdf', tumor max size to 'asdf', set patient tumor size to 5	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
162	Set protocol status to Yes, tumor min size to 'asdf', tumor max size to 'asdf', set patient tumor size to 'asdf'	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
163	Set protocol status to Yes, tumor min size to 3, tumor max size to 'asdf', set patient tumor size to empty	System should not take character values	Protocol is displayed in result grid	?	2/6/04
164	Set protocol status to Yes, tumor min size to 3, tumor max size to 'asdf', set patient tumor size to 0	System should not take character values	500 Servlet Exception Error	Failed	2/6/04

165	Set protocol status to Yes, tumor min size to 3, tumor max size to 'asdf', set patient tumor size to 5	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
166	Set protocol status to Yes, tumor min size to 3, tumor max size to 'asdf', set patient tumor size to 'asdf'	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
167	Set protocol status to Yes, tumor min size to 'asdf', tumor max size to 3, set patient tumor size to empty	System should not take character values	Protocol is displayed in result grid	?	2/6/04
168	Set protocol status to Yes, tumor min size to 'asdf', tumor max size to 3, set patient tumor size to 0	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
169	Set protocol status to Yes, tumor min size to 'asdf', tumor max size to 3, set patient tumor size to 5	System should not take character values	500 Servlet Exception Error	Failed	2/6/04
170	Set protocol status to Yes, tumor min size to 'asdf', tumor max size to 3, set patient tumor size to 'asdf'	System should not take character values	500 Servlet Exception Error	Failed	2/6/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: Cardiac Abnormality (Significant History)					
171	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
172	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
173	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
174	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
175	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
176	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
177	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
178	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

179	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
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Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: Cardiac Abnormality (Active Diagnosis)					
180	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
181	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
182	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
183	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
184	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
185	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
186	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
187	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
188	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario	Expected Result	Actual Result	Pass / Failed	Date of Test	
Protocol filtering characterizes: CNS Disease (Significant History)					
189	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
190	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
191	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
192	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
193	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

194	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
195	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
196	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
197	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: CNS Disease (Active Diagnosis)					
198	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
199	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
200	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
201	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
202	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
203	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
204	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
205	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
206	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: Brain Mets (Significant History)					
207	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
208	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04

209	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
210	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
211	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
212	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
213	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
214	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
215	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: Brain Mets (Active Diagnosis)					
216	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
217	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
218	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
219	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
220	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
221	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
222	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
223	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
224	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
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Protocol filtering characterizes: Pulmonary Abnormality (Significant History)					
225	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
226	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
227	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
228	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
229	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
230	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
231	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
232	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
233	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario	Expected Result	Actual Result	Pass / Failed	Date of Test	
Protocol filtering characterizes: Pulmonary Abnormality (Active Diagnosis)					
234	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
235	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
236	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
237	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
238	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
239	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
240	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

241	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
242	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: Prior Chemotherapy (Standard Therapy)					
243	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
244	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
245	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
246	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
247	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
248	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
249	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
250	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
251	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: Prior Chemotherapy (Investigational Therapy)					
252	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
253	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
254	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
255	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

256	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
257	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
258	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
259	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
260	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: Prior Hormone Therapy (Standard Therapy)					
261	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
262	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
263	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
264	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
265	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
266	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
267	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
268	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
269	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: Prior Hormone Therapy (Investigational Therapy)					
270	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

271	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
272	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
273	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
274	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
275	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
276	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
277	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
278	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: Prior Radiation (Standard Therapy)					
279	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
280	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
281	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
282	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
283	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
284	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
285	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
286	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
287	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario	Expected Result	Actual Result	Pass / Failed	Date of Test	
Protocol filtering characterizes: Prior Radiation (Investigational Therapy)					
288	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
289	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
290	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
291	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
292	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
293	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
294	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
295	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
296	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario	Expected Result	Actual Result	Pass / Failed	Date of Test	
Protocol filtering characterizes: Prior Vaccine/Biological Therapy (Standard Therapy)					
297	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
298	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
299	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
300	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
301	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
302	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

303	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
304	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
305	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: Prior Vaccine/Biological Therapy (Investigational Therapy)					
306	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
307	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
308	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
309	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
310	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
311	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
312	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
313	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
314	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: Any Prior Therapy (Standard Therapy)					
315	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
316	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is not displayed in result grid	Pass	2/2/04
317	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

318	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
319	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
320	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
321	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
322	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
323	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04

Test Scenario		Expected Result	Actual Result	Pass / Failed	Date of Test
Protocol filtering characterizes: Any Prior Therapy (Investigational Therapy)					
324	Set protocol to Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
325	Set protocol to Exclude, set patient to Yes	This protocol should not display	Protocol is displayed in result grid	Failed	2/2/04
326	Set protocol to Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
327	Set protocol to N/A, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
328	Set protocol to N/A, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
329	Set protocol to N/A, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
330	Set protocol to May Exclude, set patient to empty	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
331	Set protocol to May Exclude, set patient to Yes	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04
332	Set protocol to May Exclude, set patient to No	This protocol should display	Protocol is displayed in result grid	Pass	2/2/04